Q. It is not. Okay. What is your understanding as to whether the EAC component is intended to provide a profit margin to the pharmacist?
MR. GABEL: Objection.
MR. CYR: Objection.
A. It is not.
BY MR. HENDERSON:
Q. And what is your understanding as to whether or not the EAC component is meant to pay for the pharmacist's overhead in operating his business?
A. It's not.
Q. And when you recommended the discounts off of AWP in 1995, did you intend to include in that -- in the EAC component that you were developing profit to the pharmacist?
A. No.

(3/25/08 Kramer Dep., at 277:18-280:3, Henderson Reply Ex. 2.)

Defendants' Statement [45](m): Lise Farrand, Pharmaceutical Services Specialist in New Hampshire, testified:

Q. And also similar to the last first we have a section regarding reasonable dispensing fee. And New Hampshire Medicaid determined that the $1.75 was a reasonable dispensing fee based upon what other third-party payors were paying, right?
A. That's what's listed in this document.
Q. It is not based on a study that was performed on dispensing costs, right?
A. That's not mentioned here.
Q. Rather, New Hampshire Medicaid was using a survey of the market of other third-party payors, right?
A. That is what's stated here.
Q. And the same is true for Estimated Acquisition Costs in that New Hampshire Medicaid reviewed what other third-party payors were applying as a discount to the AWP, right?
A. That's what's listed here.
Q. And it -- it states that -- well, that these discounts varied from 12 to 16 percent?
A. Yes.
Q. And so based upon what other third-party payors were doing, New Hampshire Medicaid determined that a 16 percent discount off of AWP was reasonable; is that right?

A. That is what is stated here.
Q. And it wasn't based on a survey of the acquisition costs of providers for purchasing drugs, right?
A. That's not mentioned here.

* * *

Q. And today the dispensing fee in New Hampshire Medicaid is $1.75, right?
A. Yes.
Q. And the dispensing fee was not set on dispensing costs but rather it was set based upon what other third-party payors were offering as their dispensing fees, right?
A. Yes.
Q. And New Hampshire Medicaid determined that when considering the dispensing fee, it considered also the ingredient portion of the formula, right?
MR. HENDERSON: Objection.
BY MR. KATZ:
Q. The EAC portion, right?
MR. HENDERSON: Objection.
BY MR. KATZ:
Q. I'll withdraw. Let me rephrase. In considering its reimbursement methodology, New Hampshire considered both the dispensing fee portion and the EAC or ingredient portion, right?
A. Yes.
Q. And it determined that overall, the reimbursement was adequate to the providers, right?
MR. HENDERSON: Objection.
A. THE WITNESS: From reading those letters, yes.

(10/28/08 Farrand Dep. at 117:18-119:4, 165:17-166:22, Ex. 94.)

***United States' Response*:** The United States does not dispute the specific testimony quoted by defendants, but does dispute that it suggests any intent by New Hampshire to pay inflated ingredient costs in order to cross-subsidize inadequate dispensing fees. Ms. Farrand testified on this subject as follows:

Q. Have this next exhibit marked as 6. (Exhibit Farrand USA 006 for identification.)

Q. This is a state Medicaid agency regional bulletin from HCFA Region 1, HCFA now known as CMS, dated -- this is dated September 6, 1994. Did the New Hampshire Health and Human Services periodically receive bulletins from HCFA Region 1 on Medicaid issues?

A. We got -- there were paper bulletins sent to the commissioner's office. Whether or not they came from Region 1 or national, I don't know.

Q. Could you look at this and tell me whether you have any recollection of seeing it or knowing about the subject that's discussed here?
MR. KATZ: Objection, form.

A. THE WITNESS: I remember seeing something about the moratorium expiring.
BY MR. HENDERSON:

Q. Just for the record, this describes or indicates that on December 31, 1994 a moratorium expires that prohibits states from reducing the limits for covered outpatient drugs. Is it possible that you may have seen this?

A. Yes.

Q. I'd like to ask you to look at page 2 and ask you to read aloud the last paragraph of this memo starting "we would like to."

A. "We would like to clarify HCFA policy that a dispensing fee determination must be separate and distinct from the EAC determination and unrelated to the cost of the drug product. In every instance, regardless of the state determination of individual prescription payment limits, the state must have established the reasonable dispensing fees which would be used to determine whether the state is in compliance with the upper limits as specified in current regulations at 42 C.F.R. 447.331."

Q. In the mid 1990s, did you have an understanding that states should make their dispensing fee determination separate and distinct from the EAC determination?
MR. KATZ: Objection, form.

A. THE WITNESS: I see that that's what this says. I don't know that that was ever done by the state.
BY MR. HENDERSON:

Q. Well, let me ask you. When the – after the date of this, the next time when state of New Hampshire changed its or made changes to its reimbursement methodology was in relation to House Bill 32?

A. 1996.

Q. Okay. And are you aware of whether or not in determining the dispensing fee whether or not the state of New Hampshire took into account the cost of the drug?
MR. KATZ: Objection, form.
BY MR. HENDERSON:
Q. Was that part of the determination of dispensing fee?
A. No, I don't believe so.
Q. All right. And conversely, when the state determined what the EAC should be, if you know, did the state base that on the amount of costs of dispensing of the drug?
MR. KATZ: Objection, form.
A. THE WITNESS: No.
BY MR. HENDERSON:
Q. So in that regard, was the state's determination of dispensing fee separate and distinct from its determination of Estimated Acquisition Cost?
MR. KATZ: Objection, form.
A. THE WITNESS: Yes.
BY MR. HENDERSON:
Q. Are you aware of any policy or practice by the state of New Hampshire in the time that you've been working there to base Estimated Acquisition Cost in part on the cost of dispensing the drug?
A. No.
Q. And similarly, are you aware at anytime that the state has based the dispensing fee in part on the costs of acquiring the drug?
MR. KATZ: Objection, form.
A. THE WITNESS: No.

(10/24/08 Farrand Dep., at 248:21-253:1, Henderson Reply Ex. 49.) In addition, Margaret Clifford, who was the Medicaid Pharmacy Administrator for the Health and Human Services in New Hampshire from 2001 to 2005, testified as follows:

Q. At any rate, back to my question. Was one of the ways that the department encouraged the use of generics was to have a lower co-pay deducted from the reimbursement for generics as compared to branded drugs?
A. Yes.

Q. Document exhibits -- or Exhibit 5 indicates that the department in May of 1994 established a dispensing fee that was higher for generics than for branded products, correct?
A. Correct.
Q. Was that one of the ways that the department encouraged the use of generics?
A. Yes.
Q. To your recollection, at any time during your work for Health and Human Services in New Hampshire, did the department ever have a policy of encouraging the use of generics by intentionally paying an inflated Estimated Acquisition Cost?
A. No.
MR. KATZ: Objection, form.
BY MR. HENDERSON:
Q. Did, to your recollection, did the Health and Human Services ever intend to pay more than a good faith estimate of acquisition costs plus a dispensing fee?
MR. KATZ: Objection, form.
A. THE WITNESS: No.

* * *

Q. And similarly, throughout the entire time that you worked at the department -- well, I'll just -- well, I'll repeat it just so it is clear. Did the department ever determine an Estimated Acquisition Cost based upon a consideration of the cost of dispensing a drug?
A. No.
MR. KATZ: Objection to form.
BY MR. HENDERSON:
Q. And conversely, throughout the time period that you were at the department, did the department ever determine a dispensing fee based on the cost of acquiring a drug?
MR. KATZ: Objection, form.
A. THE WITNESS: No.
BY MR. HENDERSON:
Q. To your knowledge, throughout the time period that you worked at the department, did the department ever have a policy or practice of paying an inflated Estimated Acquisition Cost for the purpose of making up for an inadequate dispensing fee?
MR. KATZ: Objection, form.
A. THE WITNESS: No.

(10/29/08 Clifford Dep., at 208:18-210:2, 212:3-213:4, Henderson Reply Ex. 50.)

Defendants' Statement [45](n): Gary Cheloha, Pharmacy Consultant in Nebraska, testified:

Q. And when Nebraska determines whether or not its reimbursement methodology is adequate to providers, it has to consider both the ingredient cost and the dispensing fee together; correct?
A. It considers them separately and together, yes.
Q. Okay. Could you explain what you mean by that?
A. Well, we calculate both, with pay based on the total of the two.
Q. Okay. So in order to find out how much a particular provider is being paid for a particular claim, you would have to add the ingredient cost and the dispensing fee?
A. That's correct.

(12/2/2008 Cheloha Dep. at 81:15-82:7, Ex. 28.)

* * *

Q. And then if you go down towards the end of that second paragraph, it states: Changing the EAC calculation without considering what acquisition and operating costs currently are today, and then determining what is fair and reasonable for all, is inappropriate.
A. Yes.
Q. Sitting here today, as a 30(b)(6), do you agree that it is necessary to consider both the acquisition and operating costs, which is the dispensing and ingredient portion, prior to making any changes in reimbursement?
A. Yes.
Q. And then if you turn to the second page, it has a similar statement. It says at the very top: We are asking that the proposed change to the calculation of the appropriate discount for the EAC of drugs and the dispensing fee for each pharmacy continue to be fact-based and that neither be changed without consideration for the total reimbursement allowed to those pharmacies that choose to serve Medicaid clients. We request that HHS sponsor a new survey to determine the overall reimbursement and then implement its findings, as a number of other states have done. So once

again, this sentence speaks to the need to consider both the discount of EAC and the dispensing fee?
A. Yes.
Q. And sitting here today, do you still believe that that's an important consideration to make?
A. Yes, I do.

(*Id*. at 186:3-187:14.)

***United States' Response*:** The United States does not dispute the specific testimony quoted by defendants, but does dispute that it suggests any intent by Nebraska to pay inflated ingredient costs in order to cross-subsidize inadequate dispensing fees. To the contrary, Mr. Cheloha testified that Nebraska never adjusted its ingredient cost to compensate for perceived deficiencies in dispensing fees and that it was never Nebraska's policy to do so.

Q. (BY MR. MAO) Mr. Cheloha, I'd like to turn your attention to the second page, the last full paragraph.
A. I see that.
Q. Can you read that aloud, please?
A. We would like to clarify HCFA policy that a dispensing fee determination must be separate and distinct from the EAC determination and unrelated to the cost of the drug products. In every instance, regardless of the State determination of individual prescription payment limits, the State must have established the reasonable dispensing fees which would be used to determine whether the State is in compliance with the upper limits as specified in current drug regulations at 42 CFR 447.331.
Q. Thank you. Has Nebraska ever increased its ingredient cost reimbursement to make up for inadequate dispensing fees?
MS. LORENZO: Objection. Form.
MS. CITERA: Form.
A. THE WITNESS: No, it has not.
Q. (BY MR. MAO) Has Nebraska ever increased its dispensing fee in order to make up for inadequate ingredient cost payments?
MS. LORENZO: Objection. Form.
MS. CITERA: Form.
A. THE WITNESS: No, it has not.

Q. (BY MR. MAO) Has Nebraska Medicaid ever decreased its dispensing fee to adjust for inflated ingredient cost reimbursements?
MS. LORENZO: Objection. Form.
A. THE WITNESS: No, it has not.

(12/3/08 Cheloha Dep., at 370:2-371:12, Henderson Reply Ex. 47.) Moreover, to the extent that providers were using the ingredient cost to make up for perceived inadequacies in the dispensing fee, Mr. Cheloha testified that that was never Nebraska Medicaid's policy:

Q. (BY MR. MAO) Thank you. In your --one more question. In your extensive time with the Medicaid program in Nebraska, has it ever been the policy of the Nebraska program to use one component of the pharmacy cost reimbursement, be it ingredient cost or dispensing fee, to make up for potential inadequacies of the other component?
MS. LORENZO: Objection. Form.
A. THE WITNESS: No, it has not.

(*Id.,* at 371:13-21). Lastly, Mr. Cheloha testified that when Nebraska set its drug reimbursement rate in 1987 at AWP less 8.71 percent, it recognized that not every pharmacy would be able to procure drugs at that price, but that the state chose that rate as a balancing point between ensuring access and being fiscally prudent with Medicaid funds. Mr. Cheloha testified that these policy considerations continued when Nebraska changed its drug reimbursement formula to AWP less 10 percent and then AWP less 11 percent. (*Id.,* at 385:4-389:5).

Defendants' Statement [45](o): New Jersey's Ed Vaccaro testified that "it's entirely permissible for States to use the estimated acquisition cost, the ingredient cost portion to compensate pharmacists for inadequate dispensing fees." (12/3/2008 Vaccaro Dep. 352:09-353:11, Ex. 80.) Mr. Vaccaro also acknowledged that the state of New Jersey considered dispensing fees to be linked to ingredient costs such that "inevitably you would look at the two together."

Q. Okay. And given that this is a nationwide review comparing invoice price for drugs against AWP which -- do you agree that that is the ingredient cost portion of reimbursement?

A. Yes.
Q. Okay. Why would they discuss review of dispensing fees?
A: Dispensing fees are linked to ingredient costs.
Q. Can you elaborate further what you mean by link?
A. Well, the ingredient cost reflects the cost of purchasing a drug and a dispensing fee reflects the cost of dispensing that drug. Whether it's appropriate or not, it's what it is. It's a reflection of administrative costs for, or pharmacy costs, for dispensing the medication.
Q. Okay.
A. So inevitably you would look at the two together.

(*Id*. at 456:22-457:21.)

United States Response: Disputed. This citation is inaccurate. Mr. Vaccaro was asked whether, based on his review of an exhibit, *the Appeals Board was saying* that it was entirely permissible for States to use the EAC to compensate pharmacists for inadequate dispensing fees. Mr. Vaccaro did not make that statement. His testimony only confirmed that was what he understood the Appeals Board decision to say. Mr. Vaccaro did not testify that the New Jersey dispensing fee was inadequate or that New Jersey's ingredient cost was used to make up for low dispensing fees. In fact, Mr. Vaccaro testified that the dispensing fee in New Jersey was and continued to be adequate to reimburse pharmacists reasonably for the cost of dispensing medications. (12/3/08 Vaccaro Dep. at 458:5-9, Henderson Reply Ex. 40.) He further testified:

Q. Does your state have, currently have any practice or policy to pay inflated ingredient costs in order to make up for inadequate dispensing?
MR. KIM: Objection to form.
A. No.
Q. Has your state ever had a policy or practice of paying inflated ingredient cost in order to make up for an inadequate dispensing?
MR. KIM: Same objection.
A. No.

(12/2/08 Vaccaro Dep., at 99:4-99:14, Henderson Reply Ex.16.) Robert Stevens of New Mexico's Medicaid agency testified:

> Q. Does New Mexico have any practice or policy of paying inflated acquisition costs in order to make up for inadequate dispensing fees?
> A. No, we have specifically and intentionally not done that over the years.
> MR. JULIE: Objection to form.
> BY MR. RIKLIN:
> Q. And, in fact, you have previously testified that in your opinion the dispensing fees that New Mexico has enacted over the years are reasonable fees, correct?
> A. Yes.

(12/15/08 Stevens Dep., at 318:4 - 15, Henderson Reply Ex. 51.) Lisa Weeks of North Carolina's Medicaid gave similar testimony:

> Q. Does the state have any practice or policy of paying increased ingredient costs in order to make up for inadequate dispensing fees?
> MR. KATZ: Objection, form.
> A. No.

(10/21/08 Weeks Dep., at 77:14-77:18, Henderson Reply Ex. 34.)

Defendants' Statement [45](p): Indiana's Marc Shirley testified:

> Q. Do you think of those issues together as providing that total reimbursement must be adequate, or does reimbursement for each individual component need to be adequate?
> MS. ST. PETER-GRIFFITH: Object to the form.
> A. Once again, my sense on this is that ultimately your reimbursement for the service must be adequate to ensure participation by providers. And my sense is that providers probably don't much care one way or the other which side of the equation is which, as long as what they get from Medicaid is sufficient for them to render service.
> So I think, you know, we act administratively in light of that. It makes sense to have a total reimbursement that is sufficient to maintain provider participation.

(12/2/2008 Shirley Dep. at 145:5-22, Ex. 18.)

United States' Response: The United States does not dispute the accuracy of the transcription. However, defendants' citation to Mr. Shirley's testimony does not support paragraph 45. In the quoted material, Mr. Shirley did not testify that Indiana understood that its "state payment methodologies for drugs were designed to allow the payment of a margin on ingredient cost to encourage the dispensing of generic drugs." Rather, he simply answered a question about whether he subjectively believed that the ingredient cost and dispensing fee components of Medicaid reimbursement needed to be adequate. Moreover, Mr. Shirley's subjective beliefs are irrelevant. The quoted testimony from Mr. Shirley does not reflect any information concerning Indiana's belief about the payment of margins to encourage the dispensing of generics, whether Indiana's Medicaid dispensing fees for the drugs at issue in this case were inadequate, or whether Indiana condoned cross-subsidizing dispensing fees with mega-spreads on the ingredient costs of drugs. Further, the testimony from Mr. Shirley quoted by defendants has nothing to do with Indiana's state payment methodologies for drugs, or whether Indiana's plan authorized the payment of inflated ingredient costs mega-spreads for any reason.

46. CMS's Deidre Duzor, currently the Director of the Pharmacy Division for Medicaid, testified that she "was aware . . . that there was a spread in the ingredient cost and in some states that may have led to states not keeping their dispensing fees up to date in terms of cost to dispense because the overall reimbursement was generous." (2/27/08 Duzor Dep. at 405, Ex. 82.) Duzor acknowledged a CMS letter indicating that "Some public and private third party payors have purposely kept dispensing fee low precisely because there is a spread between AWP and AAC." (Id. at 424-27; Ex. 95 (Abbott Ex. 493).) Duzor explained that after passage of the Deficit Reduction Act, CMS acknowledged that states might need to review "their dispensing fees to assure that they are adequate to cover the cost of dispensing." (2/27/08 Duzor Dep. at 403-04, Ex. 82.) As Duzor testified that CMS understood that ingredient costs and dispensing fees were connected and that a decrease in ingredient cost meant that dispensing fees would likely increase:

Q. You, CMS, drew a connection between the two, decreasing the ingredient cost and increasing the dispensing fee, correct?

* * *

A. Yes. I would say we drew a connection. We didn't say states should reconsider. We said something to the effect of states may want to look at or should review their dispensing fees in light of changes to ingredient cost reimbursement.
Q. And you expected that the dispensing fees would increase, correct?
A. Yes. We expected that should there be a need for change it would likely be an increase.

(*Id*. at 484:8-22.) Duzor testified that CMS "didn't believe it was a violation of the regulations, but we didn't think that it was a good thing" that providers were able to keep the difference between acquisition cost and what Medicaid was paying them to cover overhead and dispensing costs. (3/26/08 Duzor Dep. at 837:16-18, Ex. 54.)

United States' Response: The United States does not dispute the existence of the testimony, but disputes its relevance and admissibility because it fails to specify a time frame during which Ms. Duzor purportedly was aware of the issue and it sets forth only subjective thoughts and speculation.

The United States disputes any assertion or inference that the testimony by Ms. Duzor or any other present or former federal official supports the contention that the reporting of inflated and inaccurate AWPs was consistent with federal regulations or policy, or that federal law or policy included any objective of "cross-subsidizing" payments for the ingredient costs of drugs. To the contrary, present and former federal officials testified that cross-subsidization in that manner was not permitted. For example, Larry Reed testified as follows:

A. There could be instances where the costs of dispensing would be different -- the costs of dispensing as determined by some studies may be different than what would be in a state's plan

as a dispensing fee. But that didn't necessarily mean that that dispensing fee was not reasonable.

Q. And why would that be?

A. Because the regulations -- and again, we have to live by the regulations so that's what I need to keep referring back to -- didn't say that reasonable meant it had to be the actual costs of dispensing. It could be determined on things like what other parties paid for that cost of dispensing, what other states paid for that cost of dispensing.

Q. And could it also not consider the profit being paid on the ingredient side?

A. Under the federal regulations it could not.

(3/18/08 Reed Dep., at 659:2-21, Henderson Reply Ex. 52.)

Q. And you would agree with me that there's no regulatory or statutory requirement anywhere that prohibits a state from paying a margin on ingredient cost reimbursement for a particular drug, correct?
MS. MARTINEZ: Objection, form.

A. No. I don't think I could agree with that.

(Id. at 683:22-684:7.)

Q. Let me try my question again. Is it your testimony that under the federal regulations a state may not subsidize insufficient dispensing fees with the margin on the ingredient cost side?
MS. MARTINEZ: Objection, form.

A. We would not -- I don't know what a state might have in its own mind in submitting a state plan amendment, but we would not approve a state plan amendment that cross-subsidized dispensing fees with an excess of ingredient costs.

Q. You believed that that would violate federal regulations, correct?

A. Correct.

(Id. at 693:15-694:6.)

47. Duzor further acknowledged that states paying very low dispensing fees would have to reassess their fees due to access concerns:

Q. Is it fair to say you can think of states where you would not feel comfortable that paying a true acquisition cost with no other changes to the reimbursement system would not be sufficient to ensure access?

* * *

A. I don't know where the line would be drawn. But I think that there may be some states that were paying very low dispensing fees where that would not be adequate reimbursement for a pharmacy.

Q. And would you feel comfortable assuming that a change to paying actual acquisition cost would not have resulted in any change to dispensing fees at any of the state Medicaid programs?

* * *

A. No. I think it may have resulted in a change in dispensing fees.

(2/27/08 Duzor Dep. at 527-28, Ex. 82.)

United States' Response: The United States does not dispute that the testimony was given, but disputes its materiality and relevance. The testimony appears to address only Ms. Duzor's present state of mind and reflection on the nature of future reform in light of the consequences of wide-spread abuse and governments' inability to counter its effects in a timely way. Such testimony has no bearing on the issues presently before the Court.

48. CMS's Larry Reed testified that CMS has had deliberations and come to a view as to the agency's position regarding cross-subsidization between ingredient costs and dispensing fees. However, Mr. Reed was unable to discuss neither the agency's position nor who from CMS was involved in the discussions regarding cross-subsidization due to the assertion of privilege by his counsel. Mr. Reed testified:

Q. Okay. And did you ultimately form a view as to the department's position on cross-subsidization between ingredient costs and the dispensing fee?
MS. OBEREMBT: Objection.

MR. DRAYCOTT: You're asking, did he form a view about the –
BY MR. MERKL:
Q. Well, did the department form a view?
MR. DRAYCOTT: About policy result, is that what you're asking?
BY MR. MERKL:
Q. No. I'm asking whether they actually came to a result.
A. Yes.
Q. Can you tell me what those deliberations were that led you to come to the result that you came to?
MS. OBEREMBT: Objection. I'm going to instruct him not to answer on the grounds of deliberative process.
BY MR. MERKL:
Q. And who was it who was involved in arriving at the view on the cross-subsidization issues?
MS. OBEREMBT: Objection. I'm going to instruct him not to answer because he hasn't said that anyone arrived at a view on cross- subsidization.

(10/2/08 Reed Dep. at 1194:11-1195:17, Ex. 55.)

United States' Response: The United States objects to defendants SOAF ¶ 48 on the ground that it fails to present any admissible evidence. Defendants seek to draw an adverse inference from government counsel's assertion of privilege. Obviously any such inference is inappropriate and inadmissible, particularly where the Special Master and this Court have generally upheld the government's assertions of privilege.

49. In a 2002 report for California, Myers & Stauffer stated:

> In fact, the acquisition cost study findings indicate that for a "typical" prescription, a pharmacy's margin on ingredient reimbursement is approximately $10. These margins on ingredient cost must be considered in tandem with an analysis of pharmacy dispensing cost and dispensing fee reimbursement in order to fully evaluate the issue of the adequacy of Medi-Cal pharmacy reimbursement.

(Ex. 96 (Myers & Stauffer, A Survey of Acquisition Costs in Pharmaceuticals in the State of

California, June 2002).) Similarly, Myers & Stauffer stated in a contemporaneous report to California that "both dispensing and ingredient reimbursement rates should be considered in tandem." (Ex. 97 (Abbott Schondelmeyer Ex. 4)).)

United States' Response: Disputed. Mr. J. Kevin Gorospe, the Chief of the Pharmacy Policy Branch of the Medi-Cal Pharmacy Benefits Division, testified that California did *not* permit or approve of inflated reimbursement on ingredient cost to subsidize for supposedly inadequate dispensing fees. (12/3/2008 Gorospe Dep., at 293:9 - 296:14, 299:3 - 299:10 Henderson Reply Ex. 32; *see infra* United States' Response to Paragraph 53.)

50. In response to questions by the Government, T. Allen Hansen, Myers & Stauffer's 30(b)(6) witness, acknowledged that Myers & Stauffer cautioned against adjusting ingredient reimbursement while ignoring dispensing fee amounts.

> Q. (By Mr. Gobena) So if I read these two recommendations together, in effect, Myers & Stauffer was recommending that the ingredient reimbursement in California in -- or in or around 2002 might be reduced -- should be reduced; is that correct?
> Q. (By Mr. Gobena) That the discount rate should be increased, probably a better way of putting it?
> A. I think the main theme of the sentences that you just read were that these changes should be considered together, that there were -- in essence, it's a caution against adjusting one and ignoring the other for the reasons stated here.

(12/11/2008 Hansen Dep. at 562:9-563:2, Ex. 98, Ex. 99 (Abbott-Hansen 005).)

United States' Response: The United States does not dispute that the statements were made, but disputes their materiality.

51. In 1999, under contract from the Louisiana Department of Health and Hospitals, Myers and Stauffer prepared a report analyzing the pharmacy dispensing costs and drug acquisition costs for providers serving Louisiana Medicaid beneficiaries. Myers and Stauffer found that "the costs to dispense I.V. prescriptions are not representative of the costs incurred by a general pharmacy" because "the activities and costs involved in filling I.V. prescriptions are significantly different." (Ex. 100 at 20-21 (Abbott Ex. 1051).) Myers and Stauffer concluded that "[a]lthough typical dispensing fees reimburse less than the dispensing costs of I.V. pharmacies, they are

generally able to break even based on the margin allowed on the ingredient cost reimbursement." (*Id*. at 21, n.6.)

United States' Response: The United States does not dispute that the statements were made, but disputes their materiality.

52. In 2001, under contract from the Kentucky Department for Medicaid Services, Myers and Stauffer prepared a report on the cost of dispensing prescription medications to Kentucky Medicaid recipients. The report was titled "A Survey of Dispensing costs of Pharmaceuticals in the Commonwealth of Kentucky." In its analysis of pharmacy dispensing costs, Myers and Stauffer found that "pharmacies that dispense I.V. prescriptions as a significant part of their business can have dispensing costs far in excess of those found in a traditional pharmacy." (Ex. 101 at 20 (Excerpt of Abbott Hansen Ex. 6).) Pharmacists interviewed by Myers and Stauffer indicated that "the activities and costs involved in filling I.V. prescriptions are significantly different from the costs incurred by the typical retail (or long term care) pharmacy." (*Id*. at 19.) In 2001, the Kentucky Department for Medicaid Services reimbursed providers who administered intravenous prescriptions based on a fixed dispensing fee plus ingredient reimbursement formula. Myers and Stuffer concluded that "[a]lthough dispensing costs at intravenous pharmacies is well in excess of the current dispensing fee, this reimbursement methodology has been accepted by these pharmacies because the margin on ingredient reimbursement has allowed pharmacies to offset any shortfall from the dispensing fee." (*Id*. at 46.)

United States' Response: The United States does not dispute that the statements were made, but disputes their materiality.

53. In 2002, under contract from the California Department of Health Services, Myers and Stauffer prepared a report titled "Study of Medi-Cal Pharmacy Reimbursement." (Ex. 97 at (Abbott Schondelmeyer Ex. 4).) The report stated: "In every dispensing cost survey performed by Myers and Stauffer in which data on the provision of intravenous services was collected, the provision of this service has been associated with higher dispensing costs. (*Id*. at 59.) Myers and Stauffer concluded that the average intravenous prescription "would yield a margin on ingredients of approximately $42." (*Id*. at 60.) The report stated: "This margin typically allows for adequate reimbursement of the pharmacy's dispensing cost. So long as the ingredient reimbursement rate remains at AWP minus 5% or any other relatively 'high' level, the need for the Department to set a separate dispensing fee for intravenous drugs is somewhat mitigated by the margins realized on ingredient reimbursement." (*Id*.)

United States' Response: The United States does not dispute the accuracy of the quotation from the Myers and Stauffer report. The United States does, however, dispute the implication that

the State of California had a policy of paying inflated ingredient costs in order to cross-subsidize dispensing fees. Mr. J. Kevin Gorospe, the Chief of the Pharmacy Policy Branch of the Medi-Cal Pharmacy Benefits Division, testified on the subject as follows:

Q. All right. Mr. Cole asked you some questions about home infusion drugs and costs associated with dispensing or administering those drugs. Did – did Abbott Laboratories ever come to the Department to your knowledge and tell the Department that the dispensing fees for its drugs were too low?
MR. COLE: Object to the form.
A. THE WITNESS: No.
BY MR. HENDERSON:
Q. Did Abbott Laboratories ever come to the Department and tell the Department that it was inflating the AWPs for its drugs because it wanted to increase the – the reimbursement for providers who purchased its drugs?
MR. COLE: Object to the form.
A. THE WITNESS: No.
BY MR. HENDERSON:
Q. Did the – did the Department ever delegate to drug manufacturers the authority to determine how much dispensing fees should be paid to providers?
A. No.
Q. Did the Department ever take a position that drug manufacturers should be permitted to report false AWP pricing information so that – in order to compensate for inadequate dispensing fees?
MR. BUEKER: Objection as to form.
A. THE WITNESS: No.
BY MR. HENDERSON:
Q. In your opinion, Dr. Gorospe, would it be a reasonable government policy to give drug manufacturers the – the power to increase reimbursements in order to make up for what they perceive to be inadequate dispensing fees?
MR. BUEKER: Objection as to form.
A. HE WITNESS: No.
BY MR. HENDERSON:
Q. Why not?
MR. BUEKER: Same objection.
A. THE WITNESS: Why not what?
BY MR. HENDERSON:

Q. Well, why wouldn't that be a reasonable policy to pursue?
MR. BUEKER: Same objection.
A. THE WITNESS: The management of the – the program is – with the State of California and with – and the federal government, and to allow a – what is considered in California a provider type, which a manufacturer is, to set rates for providers would – would not make sense.
BY MR. HENDERSON:
Q. It would give the manufacturer control over how much money is – of the State's money is spent; is that fair to say?
A. Potentially.
Q. To your knowledge has – Let me withdraw that and ask a different question. If Abbott Laboratories reported grossly inflated Average Wholesale Prices to First DataBank knowing and intending that those prices would be used by state Medicaid agencies, including Medi-Cal, to pay inflated reimbursements to customers, people who bought Abbott drugs, would you consider that to be deceptive?
MR. COLE: Objection. Form.
A. THE WITNESS: Yes.

* * *

Q. Has the Department ever had a – any policy or practice of paying inflated acquisition costs in order to compensate for perceived inadequate dispensing fees?
MR. BUEKER: Objection as to form.
A. THE WITNESS: Was it a policy?
Q. MR. HENDERSON: Yes.
A. THE WITNESS: No.

(12/3/2008 Gorospe Dep., at 293:9 - 296:14, 299:3 - 299:10 Henderson Reply Ex. 32.) In addition, Douglas Hillblom, who worked for the California Department of Health from 1993 to 2005 and was the Senior Pharmaceutical Consultant from 1995 to 2001, testified as follows:

A. THE WITNESS: Pharmacy reimbursement is a multi-component item. Cost of the drug product is only one component.
BY MR. BUEKER:
Q. The other component is dispensing fee; correct?
A. Correct.

Q. And that's a rate that was set independently of the ingredient cost reimbursement rate; is that fair?
A. Yes.
Q. And together the two had to total something that the Department considered reasonable; right?
A. Yes.
Q. But in terms of the actual calculation of the two components, the calculation of the two components, that portion of it was done separately?
A. Yes.

(9/23/2008 Hillblom Dep., at 93:16 - 94:13 Henderson Reply Ex. 10.)

54. An August 30, 2004 report prepared by Abt Associates, titled "Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices," contained the following statement:

> Most experts agree that AWP, or even the typical discounts to AWP, exceed actual acquisition costs for both pharmacies and physicians. This is particularly true for generic drugs. At the same time, these experts agree that Medicaid dispensing fees are low relative to actual dispensing costs. One panel member commented, 'If it weren't for the AWP spread, the pharmacies would be out of business.' Payments based on the cost structure experienced by pharmacies may warrant payment of a reasonable and manageable spread (an amount paid above the actual acquisition cost).

(Ex. 59 at 7 (Abbott Ex. 381).)

United States' Response: The United States does not dispute the existence of the Abt report or that it contains the quoted statement. It is obviously misleading, however, to draw inferences from only a few sentences out of a 31-page report. A more accurate summary of the report's import is found in the very first sentence, which states, "In both the Medicaid and the Medicare Part B prescription drug programs, there is a need for a payment methodology that accurately reflects the costs of products and services from efficient providers." Moreover, the Abt report's consideration of policy issues relating to options for reforming the Medicaid drug

reimbursement system is irrelevant, particularly in light of the fact that the integrity of that system has been destroyed by the conduct at issue in these cases.

55. OIG's Ben Jackson, formerly the Acting Director, Operational and Program Reviews (Health Care Financing Audit Division), was involved in OIG's two rounds of studies to determine the average discount off of AWP for brand and generic drugs. He testified that "some states could have said that the way they set their reimbursement rates for drugs could also have been tied in to how they did their dispensing fees," and that the two components "were together. [The states] looked at them as a whole and not separate." (12/12/2008 Jackson Dep. at 215:18-216:2, Ex. 37.)

United States' Response: The United States objects to the testimony as irrelevant and inadmissible. What "some states could have said" is speculative, without foundation, and of no import.

56. After Congress passed the Deficit Reduction Act of 2005, which proposed to decrease ingredient cost payments for many multiple-source drugs by calculating federal upper limits based on 250% of AMP, numerous states proposed or passed legislation to increase dispensing fees to offset the decrease in ingredient cost payment. (Ex. 102 (Abbott Ex. 488).) Deirdre Duzor, the Director of the CMS Pharmacy Division for Medicaid, testified related to this issue:

> Q. Do you have an understanding of what Louisiana's rationale was for proposing an increase to its dispensing fees?
> A. I believe part of their rationale was to offset the reduction expected in the FUL reimbursement in the reimbursement for generic drugs because of the new federal upper limit.
> Q. Have you heard that other states are contemplating an increase in dispensing fees if there would be a decrease in the ingredient base reimbursement based upon the change in the FUL calculation?
> A. Yes, I have.

(2/27/2008 Duzor Dep. at 279:18-280:8, Ex. 82.)

United States' Response: The United States does not dispute the existence of the testimony, but disputes its materiality and relevance. Ms. Duzor was discussing apparent issues relating to the new method for determining FULs mandated by the Deficit Reduction Act of 2005,

Pub. L. 109-171, 120 Stat. 4, which were subsequently suspended by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), Pub. L. 110-275. These items of legislation and the resulting policy debates do not excuse, and are not relevant to, defendants' liability. Responding further, Ms. Duzor testified that personnel at the CMS Pharmacy Division for Medicaid "generally continue to believe that most states are overpaying for the ingredient cost and, therefore, were generally interested in approving state plans that reduce the ingredient cost payment. And with dispensing fees, we are concerned that some states are paying high dispensing fees and proposing to pay even higher ones. And we are concerned that they may be overpaying in dispensing fees, so we are scrutinizing those more than we are when states want to reduce ingredient costs." (3/26/08 Duzor Dep., at 617:7-17, Henderson Reply Ex. 23.)

Responding further, the inference defendants seek to draw from isolated excerpts of testimony is contradicted by long-standing HHS policy. In a formal State Medicaid Agency Regional Bulletin, No. 94-25, dated September 6, 1994, HCFA stated:

> Regarding the establishing of reasonable dispensing fees, in the preamble to current regulations at 42 CFR 447.301-334, we stated that while we were deleting requirements that State agencies first survey dispensing fee costs before modifying their dispensing fee, we still expect that States will continue their present activities to establish a reasonable dispensing fee level and will document them in their State Plan.
>
> Such activities could include: (I) audits and surveys of operational costs; (2) compilation of data regarding professional salaries and fees; and (3) analysis of compiled data regarding pharmacy overhead costs, profits, etc. Each State should establish a dispensing fee to reflect the various characteristics of that State, e.g. per capita income, realty costs and other pharmacy operational or overhead costs, etc. The methods or standards they utilize to establish such fees are at the discretion of the individual State but should be documented in support of the State Plan.

> We would also clarify our policy that a dispensing fee determination must be separate and distinct from the EAC determination and unrelated to the cost of the drug product. In every instance, regardless of the State determination of individual prescription payment limits, the State must have established the reasonable dispensing fees which would be used to determine whether the State is in compliance with the upper limits as specified in current drug regulations at 42 CFR 447.331.

(Henderson Reply Ex. 43.)

In addition to the testimony on this subject referenced in the United States' responses to prior SOAFs, numerous other state Medicaid officials testified that the determination of the state's dispensing fees was separate from the EAC determination and that there was no policy or practice of cross-subsidizing. For example, Alaska's David Campana testified:

> Q. Now, do you have any understanding as to whether or not this profit factor is linked in any way to the amount of the estimated acquisition cost?
> A. I do not believe.
> MR. KATZ: Objection; form.
> A. I do not believe it is linked to the acquisition cost.
> Q. Do you have any understanding as to whether or not the determination of the dispensing fee is separate and distinct from the determination of the estimated acquisition cost?
> MR. KATZ: Objection; form.
> A. It's my understanding that the dispensing fee was independent of the ingredient cost, and there was – and there was a separate survey to determine a dispensing fee and then a different survey for the ingredient cost.
> Q. And those were separate efforts that the agency undertook in 1989?
> A. That is my understanding.
> Q. Do you have an understanding of what the – what, if any, policy of the Federal Department of Health and Human Services has been on whether or not the determination of the dispensing fee should be separate and distinct from the determination of estimated acquisition costs?
> MR. TORBORG: Object to form.

A. It is my understanding that they wanted those reviewed separately and determined separately.

(8/21/08 Campana Dep. at 270:20-272:1, Henderson Reply Ex. 3.) Suzette Bridges of Arkansas' Medicaid agency testified:

Q. Is it – is it your understanding that the State is supposed to make its dispensing fee determination separate from its determination of ingredient cost
A. We've always considered them a separate entity, separate – two separate things.
Q. Has Arkansas ever had any practice or policy of paying increasing ingredient costs to make up for inadequate dispensing fees?
A. No.

(12/10/08 Bridges Dep., at 68, Henderson Reply Ex. 31.) Colorado's Medicaid witness Allan Chapman testified:

Q. Do you see where it says, "If the AWP spread disappears, the dispensing fee may have to be increased"? MR. ANDERSON: Objection, form.
A. I see that.
Q. (BY MR. KATZ) Is that something that Colorado Medicaid considered when considering changes to its reimbursement methodology?
MR. ANDERSON: Objection, form.
A. Not specifically. I don't remember it that way.

(12/15/2008 Chapman Dep. at 136, Henderson Reply Ex. 4.) Mr. O'Connor of the State of Delaware testified:

Q. Does Delaware have a policy to pay inflated acquisition -- ingredient costs, I'm sorry, to make up for a dispensing fee it considers inadequate?
MS. RAMSEY: Objection.
MR. CYR: Objection.
A: No.

(12/10/2008 O'Connor Dep., at 70-71, Henderson Reply Ex. 53.)

57. The Congressional Budget Office, Congress, and CMS officials all recognized that decreases in ingredient reimbursement contemplated by the Deficit Reduction Act would necessitate increases in dispensing fees. (Ex. 103 (Abbott Ex. 520).)

- In a May 12, 2006 letter to HHS Secretary Michael Leavitt, Charles Grassley, Senate Finance Chair, stated: "CMS should make clear to states that they should reconsider their dispensing fees paid to pharmacies under Medicaid, particularly for generic drugs."

- On November 3, 2005, Senator Grassley stated during debate on the Deficit Reduction Act of 2005: "States will need to review and increase the fees that they pay pharmacies for dispensing Medicaid prescriptions. The overall assumption under the bill is that states will increase their fees to account for the fact that states would probably be paying pharmacists a lower amount for the drug product that more accurately reflects the cost of the drug being dispensed."

- In its January 27, 2005 report on the Deficit Reduction Act of 2005, the CBO stated: "The Congressional Budget Office's (CBO's) projected savings "reflect CSO's expectation that states would raise dispensing fees to mitigate the effects of the revised payment limit on pharmacies and preserve the widespread participation of pharmacies in Medicaid."

- In a November 15, 2006 meeting of the National Association of State Medicaid Directors Conference, Duzor stated: "States should be reviewing the adequacy of Medicaid pharmacy reimbursement." (*Id.*)

United States' Response: Disputed. None of the statements quoted support defendants' Common SOAF. The statement is also immaterial because it relates to the change in FULs mandated by the DRA of 2005 and subsequently suspended by Congress, and is irrelevant to the issues before the Court. In addition, one member of the Senate does not constitute "Congress." In any event, Senator Grassley was not advocating or suggesting that states increase dispensing fees in an amount commensurate with the savings to be realized by the reporting and reimbursement of

accurate ingredient costs; rather, he stated that states should determine an *accurate* dispensing fee based upon a survey of *actual* dispensing costs, and add to that a "reasonable return" for dispensing Medicaid prescriptions. (*See* November 3, 2005 *Congressional Record,* at p. S12326, Henderson Reply Ex. 54)

In further response, an examination of the increased use of MAC and FUL prices by State Medicaid programs over the past decade and dispensing fees during the same time period provides no evidence to suggest that there was a sea change in dispensing fees that accompanied the reduction in ingredient cost reimbursement for generic products. In only five out of 23 instances when a state implemented a MAC program during that time period did the state also increase its dispensing fee around the same time, with an additional two states *lowering* their dispensing fee. The average change in the dispensing fees among these 23 states was just nine cents, demonstrating that significant changes in dispensing fees would not have necessarily have occurred if defendants had reported more accurate prices for its AWPs and WACs. (4/23/09 Rebuttal Report of Mark G. Duggan, Ph.D., at p. 7, Roxane Ex. 219.)

G. Payment Rates Were Negotiated And/Or Set By State Legislatures

58. Numerous state officials explained that they arrived at their drug payment rates through a process of negotiation with legislators, Governors, Medicaid officials, and pharmacy providers. For example:

United States' Response: The United States partly disputes defendants' general statement insofar as it disregards the fact that, with very few exceptions, federal and state law and/or formal policy provided for reimbursement to be based on "estimated acquisition cost." *See* US-Common-SOF ¶¶ 29-31. In addition, the word "numerous" is too vague to meaningfully respond to, particularly given that a number of defendants' specific "examples" are incorrect, as explained

below. The United States does not dispute the general proposition that, when inflated AWPs cause inflated reimbursements, pharmacy provider associations will typically object if a state agency proposes reductions. This is a consequence of false reporting by manufacturers; it does not reflect any government approval of false price reporting, and is not indicative of what would have happened if the false price reporting had not occurred in the first place.

> *Defendants' Statement [58](a):* When CMS asked in 2001 how Illinois came to its reimbursement rate, Illinois told CMS that "[o]ur drug cost methodology was derived via two step approach which included 1) a thorough review of what other State's were doing and selecting the percentage off of AWP that was reasonable and 2) conducting negotiations with the Pharmacy Industry." (Ex. 104 (Abbott Ex. 769).)

United States' Response: Undisputed, except to the extent that defendants claim that negotiations were the sole process by which drug payment rates were set. The quoted excerpt for Illinois, for example, makes clear that Illinois was attempting to set a reasonable discount off of AWP.

> *Defendants' Statement [58](b):* Idaho advised CMS that "[r]epresentatives from the state pharmacy association, hospital association, and retailer's association met with the Department numerous times to negotiate reimbursement rates for pharmacies." (Ex. 105 (Abbott Ex. 491).)

United States' Response: The United States does not dispute that defendants have quoted a portion of the cited document accurately. Neither the cited portion of the document, nor the document in its entirety, however, indicates that Idaho set a drug payment rate solely through a process of negotiation with providers. Rather, the document cited by defendants makes clear that Idaho was attempting to set a reasonable discount off of AWP, and in doing so, consulted CMS, OIG reports, dispensing cost studies and the provider community.

Defendants' Statement[58](c): New Jersey's Ed Vaccaro testified:

Q. During your time at Medicaid -- I'm sorry. Let me clarify it. During the 1990's, was that a concern to not incur the wrath of National Pharmacy Associations when you were developing reimbursement methodology?
A. I think there was a strategy implemented by the agency starting in the early 90's and forward that brought interested parties, advocates to the table before they made decisions that impacted, for example, reimbursement.
Q. When you say agency, which –
A. Advocates. We're talking about whether it be beneficiary advocacy groups or if we were going to somehow impose changes on eligibility. In the case of pharmacy we brought the associations to the table, including Pharma, when it was appropriate to do so, for the purpose of taking in their recommendations regarding reimbursement. For example, if we were proposing a certain level of reimbursement that we knew would be antagonistic we would ask them for their own proposals as alternatives to a change in reimbursement if indeed a goal was to save dollars. That kind of thing.
So what I think you're looking at here is in the 90's our efforts to try and, you know, reduce the rhetoric, if you will, from the various professional organizations, state or national, they would bring their national advocates in with them.
Okay. And to try and work things out with interested parties ahead of time before we put something in place.

(12/2/2008 Vaccaro Dep. at 239:9-240:20, Ex. 30.)

* * *

Q. You testified earlier that in certain instances when New Jersey Medicaid had proposed reimbursement policies there were a variety of interests involved that were not affiliated with New Jersey Medicaid; is that correct?
A. That's correct.
Q. One of those interest groups were pharmacy associations; is that correct?
A. Yes.
Q. Would you agree that pharmacies had an interest in keeping reimbursement high?
A. Yes.
Q. And would you also agree that pharmacy advocacy groups place pressure on New Jersey Medicaid to keep reimbursement high?

A. Yes.
Q. You testified earlier also about the New Jersey Pharmaceutical Association; is that correct?
A. Yes.
Q. What types of, I'm sorry. What kinds of pharmacies do they represent?
A. Non chain pharmacies.
Q. Independent pharmacies; is that correct?
A. Yes.
Q. And do they represent only pharmacies located in New Jersey?
A. Yes.
Q. Do you know how many members are in that association?
A. I do not.
Q. Would it be in the hundreds?
A. Yes.
Q. Thousands?
A. Likely the thousands.

(*Id*. at 263:15-265:8.)

* * *

Q. So it's more than 50 percent of New Jersey pharmacies, independent, sorry, pharmacies?
A. It's not likely more than 50 percent because there are, I think there are five professional pharmacy organizations in the state. They sort of share who's going to be a member of what. Some are members of two associations. There's actually an association of chain drug stores, just for chain stores. That's only chain stores.

Then you have New Jersey Pharmacists Association, Garden State Pharmacy Owners, Independent Pharmacy Alliance. Those three share membership with, some pharmacies may be in some associations and not in others, so it might be in the hundreds, the high hundreds, maybe seven or eight hundred members are part of the Pharmacists Association. Same number might be in the Garden State Pharmacy Owners but there might be a duplicate membership.
Q. Okay. So you mentioned five pharmacy groups. Did they exist in the 1990's?
A. Yes.
Q. Under those names?

A. Yes.
Q. Early 1990's?
A. Definitely in mid 1990's.
Q. In 1990's?
A. I think they became stronger in the early 90's because of our transition between fiscal agents and the impact it had on the pharmacy community.
Q. I see. Were they present during any of the reimbursement proposals during the 1990, mid 1990's?
A. They would have been invited to sit with the division to talk about prospective proposals for the budget year coming up. Whether or not they actually were, you know, listened to or worked with is a different story but at least the invitation went out to have them talk to us so we would try to minimize any kind of negative impact to a policy change on them.
Q. So did New Jersey Medicaid, in fact, meet with any of these associations --
A. I would say yes.
Q. -- during the mid 1990's?
A. Yes, we would.
Q. Do you recall which ones specifically?
A. I think we met with them all as a group. We actually got to the point of inviting them all down together. Representatives from each organization would come down and sit and talk to us.

(*Id*. at 265:9-267:22.)

* * *

Q. Okay. Now, if you just go – skip a paragraph and go to the paragraph that starts with: While – while I believe, the second sentence he says, "I expect strong resistance from the provider community and a long and arduous negotiation." What does he mean by negotiation.
A. As I indicated in testimony yesterday, we often, even back in the '80s, I would imagine, we often sat across the table from professional organizations in the State, professional pharmacy organizations, to discuss our intentions regarding changes in -- typically reimbursement, and this is an example of that.
Q. Okay. And this is prior to Medicaid agencies submitting a State plan for approval?
A. Yes.

(12/3/2008 Vaccaro Dep. at 414:9-415:3, Ex. 80.)

United States Response: Undisputed.

Defendants' Statement [58](d): Colorado's Allen Chapman testified:

Q. And when Colorado set its reimbursement rate for prescription drugs, it had to set its reimbursement rate high enough to ensure that enough providers participated, right?
MR. ANDERSON: Objection, form
A: I'm sure that was one of the criteria. It wasn't the only criteria.
Q. Okay. What were some of the other criteria?
A: Studies that were done within the state, negotiation.
Q. And when you say studies, you're referring to studies regarding dispensing costs and acquisition costs?
A: Correct.
Q. And when you say negotiations, you're referring to negotiations with the pharmacy community, right?
MR. ANDERSON: Objection, form.
A: And other parties.

(12/15/2008 Chapman Dep. at 46:1-21, Ex. 11.)

United States' Response: Undisputed.

Defendants' Statement [58](e): When asked how Delaware arrived it its reimbursement rate, Cynthia Denemark testified that Delaware Medicaid "worked with the provider community leaders to establish a rate that would [] permit [pharmacies] to continue being [Delaware Medicaid] providers." (12/9/2008 Denemark Dep at 150:17-153:17, Ex. 22.)

United States' Response: The United States does not dispute the accuracy of the quoted testimony. Defendants' quotation, however, is selective, incomplete, and misleading, and therefore the United States disputes the implied import of Paragraph 58(e), particularly to the extent that defendants suggest the state of Delaware set its reimbursement solely based on input from providers.

Defendants' Statement [58](f): North Dakota considered adequacy of reimbursement levels when making overall changes to its reimbursement formula and

considered its reimbursement levels to be adequate as long as it paid the same amounts as Blue Cross Blue Shield North Dakota.

Q. And did North Dakota consider the adequacy of reimbursement when it made those changes?
A. The changes that we made with the, for instance, the MAC pricing, we used the private sector MAC pricing. So any evaluation of adequacy was solely based on the fact that this is what they get paid by Blue Cross Blue Shield of North Dakota which accounts for 80 percent of the claims in the state. Therefore, we assume it must be accurate. Or adequate. Because we were then paying the exact rates as Blue Cross Blue Shield of North Dakota.

(2/12/2008 Joyce Dep. at 74:3-15, Ex. 19.)

United States' Response: Undisputed. Further, the North Dakota 30(b)(6) witness also testified that Oregon assumed that the rates paid by Blue Cross Blue Shield of North Dakota reflected a reasonable estimate of acquisition cost:

Q. And Ms. Thomas asked you several questions about the sentence in this -- in – under item 13 on these state plan versions that states, "Estimated acquisition cost will be this agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler."
Do you remember that discussion?
A. Yes.
Q. And I believe you testified that that language has been consistent in North Dakota's state plan throughout the various changes to the state plan. Is that accurate?
A. Yes.
Q. Now when North Dakota Medicaid considered the amounts that Blue Cross Blue Shield of North Dakota paid to providers for prescription drugs, it wasn't considering the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer, was it?
MS. THOMAS: Objection. Form.
A. We would have to assume that a private company that has such market share would be paying on their definition of estimated acquisition cost appropriately.

MS. THOMAS: Objection. Form.

Q. But actually when you consider the amount Blue Cross Blue Shield of North Dakota is paying pharmacies for prescription drugs, North Dakota Medicaid was actually considering the price generally and currently paid to providers for a drug marketed or sold by a particular manufacturer or labeler, correct?

MS. THOMAS: Objection. Form.

A. No. As we would have to assume that Blue Cross Blue Shield would be paying appropriate estimated acquisition costs. Therefore, if one is doing it, they're estimating the acquisition cost to be that for the prices paid by the providers, then that same logic would then cross over to Medicaid if we used the same rates as paid by providers.

(12/12/08 Joyce Dep., at 291:8-293:5, Henderson Reply Ex. 9.)

Defendants' Statement [58](g): New Hampshire's decision to begin discounting AWP by 12% in 1996 was reached after negotiations with pharmacies. (10/28/2008 Farrand Dep at 96:15:97-21, Ex. 94, 10/29/2008 Clifford Dep at 53:3-54:12, 55:13-56:12, 174:1-7, Ex. 106.)

United States' Response: Disputed. Defendants' Paragraph 58(g) completely misstates the testimony. The testimony of Lise Farrand that defendants cite says nothing whatsoever about negotiations with pharmacies, but instead states that New Hampshire's decision to adopt an estimated acquisition cost of AWP-12 percent was made after a survey showed that other third-party payors paid similar amounts. The testimony of Margaret Clifford that defendants cite is taken out of context. It does not address the change to an EAC of AWP-12% but, instead, addresses discussions about New Hampshire's "Most Favored Nation" clause and its relationship to the EAC. In testimony omitted by defendants, Ms. Clifford clarified that New Hampshire's change to EAC-12 percent was not a result of negotiations with pharmacists:

Q. But okay. Can you tell me in your own words how the reimbursement rate went from AWP minus 10 percent plus a

variable dispensing fee to AWP minus 12 percent plus a $2.50 dispensing fee?

A. That was done through the legislature and that House Bill 32 which had nothing to do with me or the department.

Q. Okay. Did it have to do with negotiations with the pharmacy association?

A. No.

Q. Did New Hampshire Medicaid or any personnel of New Hampshire Medicaid meet with any pharmacy associations regarding this change from reimbursement from AWP minus 10 percent and a variable dispensing fee to AWP minus 12 percent and $2.50 dispensing fee?

A. No. The meetings were over the pharmacy, the pharmacy groups associations concern over the Most Favored Nation clause that was also part of that same legislation that was changing the reimbursement rate. The concern wasn't over the reimbursement rate or the dispensing fee. It was over the Most Favored Nation, and the language of that.

(10/29/08 Clifford Dep., at 58:16-59:18, Henderson Reply Ex.50.)

Defendants' Statement [58](h): Rather than try to accurately estimate acquisition costs when it changed its reimbursement rate in 2001, Wisconsin relied on information from several sources, including pharmacy representatives and reimbursement rates set by other states, to determine Wisconsin Medicaid's reimbursement formula. (Ex. 107 (Abbott Ex. 773); Ex. 108 (Abbott Ex. 1073).)

***United States' Response*:** Disputed. The Bureau Director in the Division of Healthcare Financing Bureau of Fee for Service Healthcare Benefits for Wisconsin Medicaid testified regarding the agency's efforts to accurately estimate acquisition costs in 2001.

Q. Since 1990 has – what has the State done to determine if the ingredient cost reimbursement is the best estimate of the price generally and currently paid by providers for the drug?

A. We've used First DataBank AWP listings with a discount that was applied.

Q. How does the State know what the appropriate discount is?

A. We, based on various sources and various factors, determine the discount, which has varied over the years, as I think you mentioned in '93 it was still 10 percent as noted hered. I believe as a result of a biennial budget, I think it was the

2001-2003, it went to 11.25 percent. I think in State fiscal years '04 and '05 it went from – it was raised, the discount now, was raised from 12 to 13, and it remains at 13 today. So it's – it's varied.

Q. How – I guess what I'm asking is how did the State determine that the discount was the best estimate of the price generally and currently paid by providers for the drugs?

A. Typically - we – we look at a number of sources where AWP is used. For example, what other states, particularly those in the region, discounted their products for their estimated acquisition cost. That would be one of the sources we used. Whatever we could find out from private payors as well was another source that we would use. There were reports that were done that I mentioned earlier as well.

Q. You took into consideration the reports from the OIG?

A. OIG, um-hum.

(8/16/07 Vavra Dep. at 59:15–61:5, Henderson Reply Ex. 55.) Furthermore, the documents cited by defendants consist of (1) emails between CMS employees and Wisconsin Medicaid employees, which do not state anywhere that the State had failed to try to accurately estimate acquisition costs, and (2) a briefing paper from a Wisconsin legislative committee that also does not contend that the State had failed to try to accurately estimate acquisition costs.

Defendants' Statement [58](I): Arkansas's reimbursement methodology was affected by political considerations and "provider relations issues," such as opposition from industry lobbying and concerns by those in the pharmaceutical industry. (12/10/2008 Bridges Dep at 300:15-301:6, Ex. 109; 12/11/2008 Bridges Dep at 375:13-21, Ex. 10.)

United States' Response: Disputed. The Rule 30(b)(6) representative for Arkansas specifically rejected defense counsel's use of the word "politics" when asked whether "politics played a role in Arkansas's setting of the reimbursement rate." Instead, the Arkansas representative testified that Arkansas Medicaid took into account information from the pharmacy community indicating that pharmacists could not purchase all generics at a cost of AWP – 25

percent, which was the State's proposed reimbursement rate at the time. (12/10/08 Bridges Dep., at 301:7-17, Henderson Reply Ex. 31.)

> *Defendants' Statement[58](j)*: Alaska's decisions regarding reimbursement rates were also influenced by the political process and the state had to account for "political realities," and "whether or not [the state] has the political capital to force through a change." (8/19/2008 Campana Dep at 161:18-162:8, 163:14-164:4, Ex. 8.)

***United States' Response*:** Disputed. Defendants statement is unsupported by the evidence. The testimony cited does not discuss any particular decision regarding Alaska reimbursement rates but merely addresses considerations that might apply if the State were to propose to reduce rates. *See* response to ¶ 58(a) above.

> *Defendants' Statement [58](k)*: California's reimbursement policy was substantially affected by political negotiations, provider concerns, and lobbying by pharmacy groups. (12/3/08 Gorospe Dep. at 47:18-49:14, Ex. 110.) California's Stanley Rosenstein testified:
>
> Q: Earlier it [referring to Rosenstein Exhibit 12] says – the May Revision had suggested cuts in the ingredient cost rate to AWP-40 percent for generic drugs based on the findings of the Myers and Stauffer report, correct?
> A: That's correct, uh-huh.
> Q: That would have been a closer approximation to providers' actual acquisition; correct?
> A: That's correct.
> Q: But the – you characterized the Department's position with respect to Section 73 as a "compromise."
> A: That is correct. Our – our initial position was – what was proposed in the Governor's May Revision, that's where we wanted to be.
> It – you know, it's a legislative process, and you have to work with the Legislature and advocates and come to a compromise on occasions.
>
> (5/19/2009 Rosenstein Dep. at 176:6-177:4, Ex. 111.)

* * *

Q: Would you turn back to the third paragraph there on page 93. The final sentence says, "In recognition of CPhA's contentions, the DHS modified the original May Revision proposal to AWP-10 percent for all drugs," correct?
A: That's right.
Q: Doesn't that suggest that the Department itself did compromise in its original proposal?
A: Yeah. As I said, it was a compromise. You know, we negotiated this between the legislative staff and the stakeholders.

(*Id*. at 178:7-20 (objection omitted)) California's Vic Walker testified as follows:

Q: Okay. The next section states [referring to Walker Exhibit 8] "Legislative History. This identical proposal has been made almost every year since the early 1990s, but has been fought to a standstill in every instance by the effective lobbying efforts of the pharmacy provider organizations and beneficiary advocacy organizations." Did I read that correctly?
A: Yes.
Q: And was that your understanding of – the legislative history of this proposed change to reimbursement when this document was prepared?
A: Yes

(5/21/2009 Walker Dep. at 119:10-22, Ex. 112.)

***United States' Response*:** Undisputed. *See also* US Resp. to Common SOAF ¶ 19(e) regarding California's efforts to base reimbursement on accurate data.

Defendants' Statement [58](l): Florida's reimbursement methodology was also influenced by pharmacy lobbying groups, such as the Florida Pharmacy Association. (12/15/2004 Wells Dep at 124:7-125:3, Ex. 12.)

***United States' Response*:** Disputed. Defendants' SOAF P 58(l) is not supported by the cited testimony, and Exhibit 12 attached by defendants appears to be from a different deposition. The cited testimony describes two situations. The first is where the State of Florida changed its reimbursement methodology and then afterwards a challenge, later dropped, was brought by the

Florida Pharmacy Association. (12/15/2004 Wells Dep., at 124:7-124:16, Henderson Reply Ex. 56) The second situation is simply a description of Mr. Well's having testified to a Florida Senate committee about the existing methodology in use in 2003. Mr. Wells described no connection to the Florida Pharmacy Association whatsoever in that situation. (*Id*. at 124:17-125:3.)

Defendants' Statement [58](m): Georgia's Jerry Dubberly admitted that Georgia's reimbursement formula was at least in part shaped by politics:

> Q. Is it fair to say that the reimbursement formula that Georgia Medicaid applies has been shaped at least in part by political considerations?
> MR. LAVINE: Object to form.
> A. Yes.

(12/15/08 Dubberly Dep. at 257:3-8, Ex. 24.)

***United States' Response*:** Disputed because the quoted testimony is out of context. Immediately before the cited testimony Mr. Dubberly stated that "I can't think of an example where we have made an agreement with the legislature." (12/15/08 Dubberly Dep., at 256:18-19, Henderson Ex. 12) Immediately after the cited testimony, Mr. Dubberly stated "I'm not aware of a situation where we have pulled back on reimbursement changes due to some agreement or other consideration made with the legislature." (*Id*., at 257:18-21). In addition, Mr. Dubberly was never asked and never offered any answer to any question during the entire course of the deposition which used the word "negotiation."

Defendants' Statement [58](n): James Kenyon explained that providers had to be consulted before Michigan Medicaid could make any changes in reimbursement:

> Q. Okay. Do you know why there was a requirement that the provider community be consulted with?
> A. Any changes in reimbursement has to go out for consultation.

(3/25/2008 Kenyon Dep. at 27:14-18, Ex. 92.)

***United States' Response*:** Undisputed.

Defendants' Statement [58](o): When setting reimbursement rates for prescription drugs, Oklahoma Medicaid consulted with pharmacy associations. Oklahoma's Nancy Nesser testified:

> Q. Does Oklahoma consult with any pharmacy associations in general when setting policies or rates for reimbursement of prescription drugs?
> A. Yes.
> Q. Which pharmacy associations?
> A. We consult with the Oklahoma Pharmacists Association, and there's another group called Pharmacy Providers of Oklahoma.

(12/12/2008 Nesser Dep. at 225:9-16, Ex. 7.)

United States' Response: The testimony is correctly quoted, but defendants mischaracterize it. Ms. Nesser did not testify that Oklahoma Medicaid set its drug reimbursement through negotiations with pharmacy associations. Indeed, the word "negotiation" was never used in any question nor offered in any answer to any question during the entire course of the deposition. Ms. Nesser testified that the Oklahoma Medicaid consulted with various sources of information in setting its drug reimbursement rates, including OIG reports, state surveys conducted at the direction of Oklahoma Medicaid, and interested constituencies (like pharmacy associations). (12/12/08 Nesser Dep., at 222:18-226:12, Henderson Reply Ex. 57.) To the extent Oklahoma Medicaid even "consulted" with the pharmacy associations, it was as a courtesy:

> Q. Were Medicaid providers consulted prior to making changes in general to Oklahoma Medicaid's reimbursement methodology for prescription drugs?
> A. "In general," you mean?
> Q. Was it Oklahoma Medicaid's practice to consult providers prior to making changes to its reimbursement formula?
> A. Not that I know of.

Q. You mentioned that the Oklahoma Pharmacists Association was involved to some extent in the process in 2002 to making changes to the reimbursement formula. Could you describe their involvement in that process.
A. As I recall, we, you know, certainly had a few courtesy meetings with them to address any concerns that they might have. And I don't specifically recall, but they could have made public comment at the rates and standards hearing.
Q. Why did Oklahoma Medicaid consult with the Oklahoma Pharmacists Association prior to making changes to the reimbursement formula?
A. Mainly just as a courtesy because they're the association that would represent the pharmacy providers.

(*Id.,* at 89:16-90:19). Ms. Nesser also testified that during her tenure with the Oklahoma Medicaid, she never received any complaints from the pharmacy association regarding drug reimbursement rates, that she would have been the one to have received those complaints, and that she understood the absence of complaints to mean that there was sufficient reimbursement to ensure provider participation. (*Id*., at 90:20-91:4.) Her understanding was confirmed by the fact that almost all of the 1100 pharmacies in Oklahoma participated in Medicaid. (*Id*., at 63:11-64:2.)

Defendants' Statement [58](p): Larry Iversen testified that provider's influence on South Dakota Medicaid influences its reimbursement methodology:

Q. If you look at the last sentence of this paragraph, it states, "Since Medicaid programs are operated in a political environment in which providers are stakeholders, the methodology employed in constructing the SMAC list must be sound in order to validate the appropriateness of the program as well as respond to inquiries from providers." Do you agree that the state Medicaid program is operated in a political environment?
MS. ACTON: Objection, form.
A. Yes.
Q. (BY MS. KHANDHAR) And how would you describe that political environment? What makes it political?
A. Because the state legislature approves or disapproves of the funding of the Medicaid program.

* * *

Q. They would be stakeholders in that way because the reimbursement would be important to them in terms of how much money they make and whether they make a profit, correct?
A. Yes.
Q. And providers are important to the overall South Dakota Medicaid because it would be important to South Dakota Medicaid to have enough providers in order to insure access to care, as we established earlier, correct?
A. Yes.
Q. And did the fact that the programs operated in a political environment affect the reimbursement methodologies that were adopted?
MS. ACTON: Objection to form.
A. Probably.
Q. (BY MS. KHANDHAR) And in what way do you think?
A. Again, because the legislature approves of the budget for the Medicaid program, then that relates to the reimbursement methodologies.
Q. Since the providers are stakeholders in the Medicaid program, the Medicaid program would want to keep those providers happy in order to insure that they were enrolled, correct?
MS. ACTON: Objection, form.
A. Yes.

(12/15/2008 Iversen Dep. at 91:3-93:19, Ex. 86; see also Ex. 113 (Dey Ex. 911).)

***United States' Response*:** The existence of the testimony is not disputed. However, the testimony provides no relevant factual information due largely to the objectionably vague term "political environment." Because all government activities can be characterized as "operating in a political environment," the testimony is immaterial. Moreover, Mr. Iversen stated that providers are stakeholders in the Medicaid Program but not the political process.

Q. And how are providers stakeholders in the political process?

A. I believe that actually that providers are stakeholders in terms of the Medicaid program, not necessarily the political process.
Q. And how are they stakeholders in the Medicaid program?
A. Because they are enrolled providers, they agree to accept what the reimbursement rates are from Medicaid and serve Medicaid recipients. That makes them stakeholders.

(12/15/08 Iversen Dep., at 92:4-14, Henderson Reply Ex.38.)

Defendants' Statement [58](q): When asked to explain in 2003 how its reimbursement rate of AWP – 11% plus a dispensing fee of $3.91 was its "best estimate," Oregon provided the following statement to CMS: "The October 4, 2002 legislative Emergency Board directed the Department to increase the rates to institutional pharmacies to AWP - 11% plus dispensing fee of $3.91. Oregon submitted a SPA exactly as requested by this legislative body, and the documentation was previously submitted with SPA 02-06." (Ex. 114 (HHC020-0382).)

United States' Response: Undisputed.

H. Attempts To Reduce Payment Rates To Acquisition Cost Were Rejected

59. Evidence demonstrates that efforts to state Medicaid reduce payment rates were curbed or defeated by political pressure from pharmacist and provider groups, or because state decision-makers did not believe reductions in ingredient cost were appropriate or warranted. For example:

United States' Response: The United States disputes the title of Section H and the general statement of Paragraph 59 as unsupported by the evidence set forth in the following subparagraphs. The United States does not dispute the general proposition that, when inflated AWPs cause inflated reimbursements, pharmacy provider associations will typically object if a state agency proposes reductions. This is a consequence of false reporting by manufacturers; it does not reflect any government approval of false price reporting, and is not indicative of what would have happened if the false price reporting had not occurred in the first place.

Defendants' Statement [59](a): On August 30-31, 1994, officials from CMS, OIG, and various state Medicaid programs met to discuss OIG's nationwide review of the

difference between the invoice price for drugs and AWP, for pharmacy providers. (Ex. 115 (Abbott Ex. 581).) OIG's "Record of Discussion" of that meeting includes the following statement:

> The state officials expressed concern that our review was limited to one aspect of pharmacy reimbursement. They said that any effort to lower the reimbursement for acquisition cost should also include some review of dispensing fees. They stated that we should include a fifth category of pharmacies to include non- traditional retail pharmacies such as hospitals, home IV, nursing homes, physicians etc ... The state officials believed that these pharmacies purchased at substantially bigger discounts than traditional retail pharmacies. They also stated that we should request the largest invoice from each different type of supplier rather than just the largest invoice.

(*Id.*)

United States' Response: Undisputed.

Defendants' Statement [59](b): On September 27-28, 1995, officials from CMS, OIG, and various state Medicaid programs met to discuss the results of OIG's nationwide review of the difference between the invoice price for drugs and AWP, for pharmacy providers. (Ex. 116 (Abbott Ex. 582).) OIG's "Record of Discussion" of that meeting includes the following statement:

> We presented the results of our AWP review. The State officials believed that our results were in line with what they had anticipated and confirmed that current State practices of reimbursing ingredient cost below AWP was appropriate.
>
> We reviewed a draft copy of a State report. The State officials believed that the report should include the following disclaimer:
>
> 'Our review was limited to ingredient acquisition costs and did not address other areas such as: the effect of Medicaid business as a contribution to other store sales; the cost to provide professional services other than dispensing a prescription such as therapeutic interventions, patient education, physician consultation: and the cost of dispensing which includes costs for computers, multi ....part labels, containers, technical staff, transaction fees, Medicaid specific administrative costs, and general overhead. We also did not take into consideration the effect of Federal upper limits amounts on generic drug reimbursements or usual and customary charge limitations.'

> The State officials were concerned that without the above disclaimer, that uninformed State officials might overreact to our report and adjust pharmacy reimbursement without considering the other aspects of reimbursement.
>
> The State officials also expressed a desire re to obtain a copy of the data reviewed for their respective States so that they could analyze. Ben Jackson said that we could provide this data.

(*Id.*)

United States' Response: Undisputed.

Defendants' Statement [59](c): In 1997, the OIG issued a report to Maryland stating that Maryland pharmacists were purchasing generics at an average 41.9% discount below AWP. (Ex. 117 (Abbott Ex. 1064).) Maryland's Joseph Fine testified regarding the report:

> Q. I'll hand you what we've marked previously as Abbott Exhibit 1064 this is a report dated February 1997 titled "Review of pharmacy acquisition costs for drugs reimbursed under the Medicaid prescription drug program of the Maryland Department of Health and Mental Hygiene." It also includes a cover letter. Have you seen this document before?
> A. Yes.
> Q. Did you receive a copy of it on or around the time it was prepared by OIG?
> A. Yes.
> Q. Do you recall any discussions within the department about this report?
> A. The discussion was there was no conclusion that we didn't already know. That was the internal discussion on this.
> Q. Did you play any part in preparing Maryland's response to the report that's the last two pages of the exhibit?
> A. Yes.
> Q. What was your involvement?
> A. I was more interested in the wholesale acquisition cost methodology as a stabilizer for inconsistent average wholesale prices. And that was my part in this.
> Q. Go to the Bates page ending 630, the section for generic drugs. At the top it states "We estimate that invoice prices for

> generic drugs were discounted 41.9 percent below AWP," correct? Is that right?
> A. That's what it says here.

(12/09/08 Fine Dep. at 238:5-239:13, Ex. 91.) An internal Maryland document discussing OIG's findings, dated April 16, 1997, contained the following statement:

> The Maryland reimbursement rate could be reduced by shaving a few more points off the AWP price. One good reason for this would be to prevent the reimbursement for brands drugs being more attractive than for generics. . . . But the Program did not change from AWP-10% in the current regulation amendments due to the possibility of strong objections from pharmacy providers.

(Ex. 118 (Abbott MD Ex. 30).)

United States Response: Disputed. Mr. Fine did not testify that efforts to reduce payment rates were defeated by political pressure or because reductions were determined to be unwarranted. To the contrary, Mr. Fine testified that Maryland relied on WAC, and not AWP, because it believed that WAC accurately represented acquisition costs to the wholesalers and that pharmacies could not purchase drugs for lower than WAC. (12/9/08 Fine Dep. at 229:8-235:18, Henderson Reply Ex. 46) Mr. Fine also testified that Maryland's aggressive use of an "interchangeable drug list" – essentially a state MAC – was an attempt to insulate Maryland from fluctuations in AWPs. (*Id*., at 320:2-321:9)

Defendants' Statement [59](d): In 1996, Virginia Medicaid received and responded to OIG's 1996 survey of pharmacy acquisition cost for drugs reimbursed under the Virginia Medicaid program. (Ex. 119 (Roxane VA Ex. 5).) The report found that in Virginia the "overall estimate of the extent that AWP exceeded pharmacy purchase invoice prices was 17.2 percent for brand name drugs and 45.1 percent for generic drugs." (Id.) In its response to a draft of the report, Virginia stated:

> DMAS appreciates the recommendation that Virginia Medicaid consider the results of this review as factor in any future changes to pharmacy reimbursement for Medicaid specific drugs in the state program. As stated Medicaid reimbursement rates to pharmacy

> providers for covered outpatient prescription drugs consist of two components which are an amount representing the drug ingredient cost the acquisition cost and an amount representing the professional or dispensing fee. Normally the reimbursement cost is based on the lower of EAC estimated acquisition cost usual and customary or FUL Federal Upper Limit and Maximum Allowable Costs. As stated in the draft of these reviews the acquisition cost is just one factor involved in pharmacy reimbursement policy or methodology and with any change consideration should be given to other factors such as the following
>
> - Impact on recipient access to service
> - Present rebate allowances from pharmaceutical manufacturers to both federal and state programs
> - Provider specialty care or level of care such as Home Health providers Coordination of monitoring for recipients with compliance needs
> - Overhead costs for dispensing functions and record keeping
>
> This does not necessarily cover inclusively that factors that are involved in assuring that the Medicaid recipient receives the most efficient and cost effective health care available, but does emphasize that when one aspect of the equation is affected, all possible consequences should be considered.

(*Id.*). Virginia continued to use an EAC of AWP – 9% for both generic and branded drugs until 2002, when it was changed to AWP – 10.25%. Virginia decided against changing its definition of EAC at that time it received the 1996 OIG Virginia report. Virginia's Bryan Tomlinson testified:

> Q. In the conclusions and recommendations of the OIG, in this report, covered the acquisition costs to pharmacies in Virginia, it is recommending the following: "We believe that the difference between AWP and pharmacy acquisition costs, as determined by our review, is significant enough to warrant consideration by the state in any evaluation of the drug program. Therefore, we recommend that the state agency consider the results of this review in determining any future changes to pharmacy reimbursement for Medicaid drugs." Correct[?]
>
> A. Yes.

Q. And you understand that the OIG is recommending to DMAS that it should take under advisement the findings of this report?
A. Yes.
Q. And those findings were that branded drugs were typically acquired at discounts of AWP minus 17.2 percent in Virginia, and that generic drugs were acquired, on average, at 45 percent discounts off of AWP, correct?
A. That was their findings, yes.
Q. And DMAS's response to these findings was not to change its reimbursement methodology, it's determination of estimated acquisition cost, correct?
A. There was no change during that time period.

(11/3/2008 Tomlinson Dep. at 251:16-253:1, Ex. 120.)

United States' Response: The United States does not dispute the existence of the evidence or the accuracy of the quotation. The United States does dispute that the evidence supports the general statement in Paragraph 59. The quoted response to an HHS-OIG report by the Virginia Department of Medical Assistance (DMAS) does not reference any belief by DMAS that reductions were inappropriate or unwarranted. Instead, the report details the factors that DMAS believed it must consider when making an overall change to the state's reimbursement methodology.

Defendants' Statement [59](e): In 1996, Montana Medicaid received and responded to OIG's 1996 survey of pharmacy acquisition cost for drugs reimbursed under the Montana Medicaid program. (Ex. 121 (Abbott Ex. 327).) The report found that in Montana the "overall estimate of the extent that AWP exceeded pharmacy purchase invoice prices was 16.2 percent for brand name drugs and 48.5 percent for generic drugs." (Id.) In its response to a draft of the report, Montana stated:

> It is important to note that the study did not investigate the payment of these services by Medicaid, only the cost of acquisition of the drug by the providers. We believe all states involved are concerned that if these numbers are directly compared to the discounted AWP method of Medicaid Pharmacy pricing, confusion and questions will arise. The two major factors that must also be considered if this

> comparison is done relate to the dispensing fee portion of the payment formula and the effect of Federal upper limit (FUL) pricing for generic drugs. No work was performed by the OIG to determine how total reimbursement for pharmacy services relates to the cost of providing the service.
>
> It is expected that when these results are published that the immediately concerns will be raised that pharmacy providers are being reimbursed more than the acquisition cost of the products and that changes should be made to the pricing formula to increase the discount on AWP. In order to address these concerns, states must do additional work to determine whether the cost to dispense is being accurately reimbursed and what effect the FUL pricing has on the discount for generic. In Montana we currently believe that the dispensing fee is below the cost to dispense because of the capon dispensing fees that is currently in place and has been for many years.

(*Id*.) Montana did not change its EAC formula (AWP minus 10%) in response to OIG's report.

United States' Response: The United States does not dispute the existence of the evidence or the accuracy of the quotation. The United States does dispute that the evidence supports the general statement in Paragraph 59 above. The United States notes that Montana changed its EAC formula from AWP-10% to AWP-15% effective October 1, 2002, and also sued drug manufacturers for false price reporting.

Defendants' Statement [59](f): In 1996, Missouri Medicaid received and responded to a draft of OIG's 1996 survey of pharmacy acquisition cost for drugs reimbursed under the Missouri Medicaid program. (Ex. 122 (Roxanne Ex. 144).) The report found that in Missouri the "overall estimate of the extent that AWP exceeded pharmacy purchase invoice prices was 18.5 percent for brand name drugs and 46.4 percent for generic drugs." (Id.) In its response to a draft of the report, Missouri stated:

> It was recognized in the 1990-91 study, as in your report, that ingredient cost is only one component to be considered in determining an appropriate pharmacy reimbursement level. Please note, that in September, 1991, the ingredient cost portion of the methodology was reduced to the amount reflected in the study; the

> standard professional dispensing fee was not raised to the recommended rate of $6.56 for independent pharmacies and $6.20 for chain pharmacies. The current standard dispensing fee of $4.09 remains below the established cost to dispense, as identified in the 1990-91 study ($5.69 for independent and $5.45 for chain pharmacies).
>
> One of the goals of DSS is to optimize the access to and the quality of health care services to the department's clients, partners and stakeholders. Toward that end, we must identify and take into consideration as many essential variables as possible in order to develop reimbursement policies that are adequate for providers and fair to Missouri taxpayers.

(*Id.*) Missouri did not change its EAC formula (AWP minus 10.43%) in response to OIG's report.

***United States' Response*:** Admitted that Missouri did not change its EAC formula in response to OIG's report. Otherwise, disputed. The cited references do not support defendants' contention that "efforts to state Medicaid reduce payment rates were curbed or defeated by political pressure from pharmacist and provider groups, or because state decision-makers did not believe reductions in ingredient cost were appropriate or warranted."

Defendants' Statement [59](g): In 1996, Florida Medicaid received and responded to OIG's 1996 survey of pharmacy acquisition cost for drugs reimbursed under the Florida Medicaid program. (Ex. 51 (Abbott Ex. 84).) The report found that in Montana [sic] the "overall estimate of the extent that AWP exceeded pharmacy purchase invoice prices was 20.2 percent for brand name drugs and 41.5 percent for generic drugs." (Id.) In its response to a draft of the report, Florida stated:

> Comparing acquisition costs for Florida pharmacies to AWP, as an academic exercise, proves that pharmacies, like almost all retail businesses, purchase goods at some discount below suggested list prices, but does not provide an indication of need to change current reimbursement policy. . . .
>
> We can conclude from the survey results that some manufacturers do not correctly report promotional prices for competitive products and the reported EAC price may be inflated by as much as a factor often

> times actual cost. most [sic] of these cases, Florida imposes the federal upper limit price which also does not fully capture all available discounts and pharmacies may still have significant markups. In most cases, the products are multi-source. Restricting reimbursement to actual cost might have the unintended effect of discouraging purchase of promotional products and eventually shifting the market to single-source products which are universally much more costly. The average multi-source prescription costs Medicaid less than $11 and the average single -source product averages over $45.

(*Id.*) Florida did not change its EAC formula in response to OIG's report.

United States' Response: Disputed because the response of Florida has been quoted out of context. The defendants fail to quote the portion of the memo revealing that Florida had reviewed the OIG data files and found that most of Florida's reimbursement was already within 10 percent of "net acquisition cost." Another portion of the Florida response omitted by defendants stated that the reported prices on "injectable products and associated intravenous fluids continue to be problematic" and asked for help in that market to have prices be reflective of the "favorable pricing and terms" offered to most vendors on those products. Another omitted portion was Florida's conclusion that its methodology already "precluded most gaming of the system through deliberate inflation of suggested AWP levels by wholesalers or manufacturers." Each of these comments reveal that Florida was attempting to set reimbursement at a level close to the "net acquisition cost" and that a change was necessary for some products (injectable products and associated intravenous fluids) where that was not happening. Thus, the Florida response supports the opposite conclusion from that claimed by defendants.

Defendants have also quoted language related to the usage of multi-source prescriptions as compared to single source prescriptions to suggest that state Medicaid programs wanted to

encourage multi-source use to save money. However, that information does not imply approval of defendants' false price reporting. For example, Abbott's vancomycin had a Red Book AWP in 2001 of $76.42 per gram, based on a 10-pack price of $764.16. (Lavine Decl. Ex. 1, (Declaration of Patrick Ormond (Ormond Decl.), Appendix B2, page 7 (Doc. #6302) and Lavine Decl. Ex. 40A, 2001 Red Book, page 550) (Docket 6305).) However, at the same time the brand name product manufactured by Eli Lily had an AWP of just $15.80. (Lavine Decl. Ex. 40A, 2001 Red Book, page 550 (listed under the brand name product Vancomycin) (Doc. #6305)). Clearly, the generic is not the economical choice, and the reverse of what is suggested by defendants would be true.

The United States also notes the inconsistency of defendants' reliance on the OIG audit which is based on 11 states, with the Florida portion based on a review of less than 3,800 invoices relating to 40 pharmacies collected during one year. Apparently, defendants deem such a limited audit to be sufficiently informative to form the basis upon which to set government reimbursement policy. However, defendants simultaneously challenge the damage calculations of the United States' expert which relied upon 10, 14 or 16 states and millions of claims per state, in effect including every invoice and every pharmacy in the review.

> *Defendants' Statement [59](h)*: In 1996, California Medicaid received and responded to a draft of OIG's 1996 survey of pharmacy acquisition cost for drugs reimbursed under the Missouri Medicaid program. (Ex. 123 (Abbott Ex. 325).) The report found that in California the "overall estimate of the extent that AWP exceeded pharmacy purchase invoice prices was 17.5 percent for brand name drugs and 41.4 percent for generic drugs." (Id.) In its response to a draft of the report, California stated:
>
> > We received your correspondence and the copy of the draft report on February 28, and have reviewed the results of the audit contained in the draft report. The draft report data indicates that a reduction in our drug ingredient cost reimbursement would be appropriate at this time. DHS intends to use these results, when published in the final report, to support a provision of our Governor's budget proposal to

> decrease drug ingredient reimbursement. The audit results will, hopefully, substantiate DHS' position that current drug ingredient cost reimbursement by the Medi-Cal program does not reflect actual purchasing activity of California pharmacies.

(*Id.*) California did not change its EAC formula (AWP minus 5%) in response to OIG's report.

United States' Response: Undisputed, except that the United States partly disputes the last sentence of Paragraph 59(h) for the reasons stated in response to Paragraph 19(e) above (relating to California's efforts to base reimbursement on accurate data).

Defendants' Statement [59](I): In addition to Maryland, Virginia, Montana, Missouri, Florida, and California, OIG issued reports in 1996 and 1997 to Delaware, District of Columbia, Nebraska, New Jersey, and North Carolina. With the exception of New Jersey, which reduced its reimbursement rate from AWP minus 2 to 8% to AWP minus 10%, none of these five states changed their EAC formulas in response to OIG's report. In August of 1997, OIG issued a report to all states showing the result of their 11-state survey that the average discount off of AWP for generic drugs was 42.5%. (Ex. 50 (Abbott Ex. 158).) In that report, OIG also informed the states of the article published by Forbes on June 10, 1996 titled "Hooked on Drugs," which found that the true cost was 10 to 20 percent below AWP for brand name drugs and 60 to 85 percent below AWP for generic drugs. (Id.)

United States' Response: Undisputed; however, the United States disputes the materiality of the statement because it fails to evidence approval of defendants' false reporting practices.

Defendants' Statement [59](j): New Jersey's Ed Vaccaro testified:

Q. And were changes in the reimbursement ate for pharmacies contested?
A. Yes.
Q. And by whom?
A. The pharmaceutical associations typically contested it.

(12/2/2008 Vaccaro Dep. at 69:7-12, Ex. 30.)

* * *

Q. And why didn't the general assembly adopt all of the cost contain measures proposed by DMAHS?

A. We work in a very strong political environment in New Jersey that's sensitive to the wants and needs of constituents, typically, demonstrated to the legislature through lobbying efforts. Inevitably, these efforts would result in certain initiatives that we would propose being turned down.
Q. And were, I think you mentioned pharmacy associations?
A. Yes.
Q. What are the names of some of those pharmacy associations?
A. Garden State Pharmacy Owners. New Jersey Pharmacists Association. Pharma. Pharmaceutical Manufacturers Association. IPA, Independent Pharmacy Association. 1, 2, 3, 4. Of course, the Association of Long Term Care Pharmacy Providers. That's pretty well it.

(Id. at 82:18-83:16.)

* * *

Q. . . . Knowing that there was a approximate 40 percent discount between -- off of AWP, New Jersey decided, nonetheless, to reimburse at AWP minus 10 percent.
Q. Correct?
A. Correct.
Q. Okay. Why didn't New Jersey decide to reimburse at AWP minus 20 percent which was the approximate discount off of generics that are dispensed in New Jersey Med -- in New Jersey?
MS. YAVELBERG: I think you meant brands.
MR. KIM: Oh, I'm sorry. Did I say generic?
MS. YAVELBERG: You said generic.
BY MR. KIM: Okay. Correction. I meant brands.
A. Okay. The decision is – is likely the result of the outcome of the open budget process where we invited providers to the table to discuss changes proposed for the budget year and they may have proposed something greater than the 10 percent and end up coming down to 10 percent because of the need to satisfy the political process effectively.

(12/3/2008 Vaccaro Dep. at 484:04-485:14, Ex. 80.)

* * *

Q. Okay. Did New Jersey at this time consider having a tiered reimbursement?
Let me explain what – what I mean by that, is having a reimbursement rate for generics and a reimbursement rate for brands with different percentage discounts.
A. In the mid '90s?
Q. In 1995 or '96 when the AWP minus 10 percent proposal was being considered.
A. It might have been proposed, but never got through the first step of the open budget process. It might have been an idea that the Division supported, but never moved any further 'cause I know later than that time, that's why I asked the year, it was proposed that we split again. It never – it never won support, sufficient support to get adopted.

(Id. at 486:16-487:10.)

* * *

Q. Okay. Sir, you mentioned that there was once a proposal that did not go through eventually, but it was a proposal that separated the – or had diff – different discounts off of AWP for generics and – and brands?
A. Correct.
Q. Okay. And you also mentioned that this proposal did not go through because of political pressures?
A: That's correct.

(*Id*. at 578:1-11.)

* * *

Q. Okay. New Jersey knew that other states had been using their own MAC separate and apart from the Federal upper limit; is that correct?
A. That's correct.
Q. Back in the late 1990s?
A. Yes.
Q. Okay. And what prevented New Jersey from implementing a state maximal allowable cost program?
A: One could attribute it to the political environment in New Jersey, reactions from the provider community.

(*Id*. at 577:8-21.)

* * *

Q. Did – switching to a different topic. Did New Jersey consider putting in place its own state MAC as opposed to just using the FUL.
A. Eric, I can tell you that we probably have – have considered that proposal two or three times in my career with the – with the State.
Q. And why did New Jersey elect not to do that?
A. Same reason as the other times. We had to deal with the political fallout, the strong negative reaction from pharmacies. It just never – there was never enough support mustered to get that kind of initiative approved in New Jersey.
Q. If – if you had initiated the MACs that were considered, would you believe that that would have lowered reimbursement payments to pharmacies?
A. Absolutely.
Q. I mean that's why they were protesting it; right?
A. Yes. And you -- you might -- you might actually hear about that kind of initiative in some very short-term future budget periods, so it's still out there. It hasn't disappeared.
Q. And in terms of . . . implementing the MAC, that is something that New Jersey could have done; right, other – other than the fact that they were prevented from doing so by the pharmacy?
A. Absolutely, that would not have been that difficult to do.

(*Id*. at 681:19-683:1.)

Q. Well, it was – it was clear -- it was clear to New Jersey Medicaid and the providers that whatever MAC was put in place would have – would have resulted in reimbursement to the pharmacies that it was even lower than whatever the reimbursement was at that time?
A. Yes, that's true.

(*Id*. at 684:9-15.)

United States Response: The United States objects to the testimony as based on hearsay and speculation and lacking in foundation. The United States does not dispute that Mr. Vaccaro testified that efforts to reduce payment rates were curbed or defeated by political pressure from pharmacy and provider groups. He also testified that pharmaceutical companies and PhRMA, the manufacturers' trade association, played a large role in the discussions, lobbied legislators directly, and tried to discourage reduction in reimbursement or the creation of preferred drug lists. (12/2/08 Vaccaro Dep., at 83:9-84:12, 89:5-90:6, Henderson Reply Ex. 16; 12/3/08 Vaccaro Dep., at 757:19-758:8, Henderson Reply Ex. 40.)

Defendants' Statement [59](k): When Louisiana Medicaid attempted by emergency rule to reduce pharmacy reimbursement to AWP – 15%, the state legislature overturned the emergency rule by overwhelming vote. (3/31/2008 Terrebonne Dep. at 133:20-141:19, Ex. 25.) Ms. Terrebonne testified related to the overturned emergency rule:

BY MR. TORBORG

Q. Do you recall a time back in early 1989 when the department attempted to enact an emergency rule to lower reimbursement from AWP minus 10.5 percent to AWP minus 15 percent?

A. Yes.

Q. And what happened?

A. Lots of things happened.

Q. Tell me about what happened.

A. I don't know that I can remember everything that happened, but there was an emergency rule to lower the ingredient cost, and there were a lot of complaints and I can't tell you the chronology of events, but Myers and Stauffer conducted a survey, and they determined a reasonable discount off of AWP, and the department did rule making and a state plan amendment and changed the reimbursement formula at that time

* * *

Q. And it says there, in the first paragraph, "Members of the House Health and Welfare Committee voted overwhelmingly to overturn an emergency rule issued by David Hood,

secretary of the Louisiana Department of Health and Hospitals, which amended the reimbursement methodology to limit payments for prescription drugs from AWP minus 10.5 percent to AWP minus 15 percent." Do you see that?
A. Yes.
Q. Do you recall that being the case?
A. Yes. There was a lot of activity in 1999.
Q. And this activity that you refer to in 1999 was a result of simply attempting to reduce reimbursement for brand name drugs from 10.5 percent to 15 percent, correct?
A. As it is written here, yes.
Q. Do you have a general idea, Ms. Terrebonne, of what the difference between AWPs and AMPs are?
A. I do not.
Q. Do you believe it is more than 4.5 percent for brand name drugs?
A. I don't know.
Q. If it was larger than 4 percent, could one presume that any attempt to use AWP information in the reimbursement methodology would have engendered the same type of activity that you saw in 1999 when you attempted to go to AWP minus 15 percent?
MR. FAUCI: Objection, form.
THE WITNESS: Had they used AMP rather than AWP?
Q. Yes.
A. Perhaps so, yes.
Q. Why would you say that?
A. Because it is always very much a provider issue when there is any change in reimbursement. Providers are very concerned.

(*Id*. at 133:20-134:14, 1401:1-141:19.)

United States' Response: Undisputed that Louisiana legislature overturned an "emergency rule" seeking to lower reimbursement from AWP - 10.5% to AWP - 15%, except that this occurred in 1999, not 1989. Further answering, the emergency rule proposed to lower the reimbursement rate to AWP - 15% following a survey performed by Myers and Stauffer showing an average discount of AWP - 17% for branded pharmaceuticals. (Exhibit Abbott 102, Henderson Reply Ex. 58; 3/31/2008 Terrebonne Dep., at 134:18, 138:4 - 138:9, Henderson Reply Ex. 13.)

Although the emergency rule was reversed in 1999, Louisiana ultimately did lower its reimbursement to AWP - 15% in February 2000. (11/7/2008 Terrebonne Dep., at 145:1 - 146:14, Henderson Reply Ex. 39.) Ms. Terrebonne testified that she does not recall any pharmacies wanting to leave the Louisiana Medicaid program following this change. (*Id.*)

Defendants' Statement [59](l): Internal documents, dated in 1997, from the state of Washington contain the following language:

- "cutting [the] % of AWP would be an extreme barrier to access some pharmacies would have to stop serving Medicaid clients." (Ex. 125 (JDWA-000107-08).)
- "no one can survive a 33% budget cut & continue to provide quality" care.(Ex. 126 (JDWA-000144).)

A 1997 letter from Washington state representative Tom Huff stated that the legislature had the "intent to avoid the drug ingredient payment reduction, if at all possible." (Ex. 127 (JDWA000233).)

***United States' Response*:** The United States disputes the admissibility of the proffered evidence, and disputes defendants' assertion in Paragraph 59(l) that the cited documents are "internal documents . . . from the State of Washington." Although the United States does not dispute that the documents were produced in response to a subpoena to the State of Washington, defendants' Exhibits 125 (JDWA-000107-08) and 126 (JDWA-000144) contain no identifying information as to who prepared them, when they were prepared or for what purpose they were prepared. Consequently, they are inadmissible hearsay. The United States further notes that the cited portion of defendants' defendants' Exhibit 127 (JDWA000233) is a letter from a single member of the State of Washington House of Representatives. Notwithstanding the foregoing, the United States does not dispute that industry lobbyists, including those representing defendants, often fought changes to Medicaid drug reimbursement methodologies, including reductions to

AWP or changes from an AWP-based reimbursement system. *See* United States' responses to paragraphs 59 above, and 98-99 below.

Defendants' Statement [59](m): In 1999, Myers & Stauffer provided Wyoming Medicaid with a report that showed that the average acquisition cost for generic drugs without a FUL was AWP – 61.8%. As a result of the Myers & Stauffer report, Wyoming changed its reimbursement rate in 2001 from AWP – 4% to AWP – 11%. Wyoming's Roxanne Homer testified:

> Q. As of 1999, Wyoming Medicaid was aware that the average actual acquisition cost for generic drugs without a [federal] MAC was AWP minus 61.8 percent?
>
> * * *
>
> A. Yes. This would have been in the report that we had. That we had, yes.
> Q. (BY MS. LIEBERMAN) Wyoming Medicaid changed its reimbursement rate for prescription drugs in 2001, correct?
> A. Yes, that's correct.
> Q. Wyoming Medicaid did not set its estimated acquisition cost at AWP minus 61.8 percent, which was the average actual acquisition cost of which it was aware that providers purchased generic drugs that were not MAC'd, correct?
>
> * * *
>
> A. No, we did not set a separate reimbursement fee for generics at that time.

(12/2/2008 Homar Dep. at 183:2-21, Ex. 128; see also Ex. 129 (Roxane WY Ex. 8).) In its State Plan Amendment 01-004, Wyoming Medicaid informed CMS that it arrived at AWP – 11% by using information gathered for the "purpose of determining a reasonable profit" for providers. (12/2/2008 Homar Dep. at 192:13-14 Ex. 128; Ex. 130 at WY00000074 (Roxane WY Ex. 9).) At the same time that it reduced the ingredient cost component of its reimbursement formula to AWP-11%, Wyoming simultaneously increased the dispensing fee component to compensate in part for the decrease in reimbursement. Ms. Homer testified:

> A. I think that – to the best of my recollection, we felt like we needed to give at least a small bump in the dispensing fee if

we were going to decrease the overall reimbursement related to AWP.

Q. So in making the decision to increase the dispensing fee, would it be fair to say that Wyoming Medicaid considered the dispensing fee portion of reimbursement together with the ingredient portion of the reimbursement formula?

A. Yes.

(12/3/2008 Homar Dep. at 497:22-498:10, Ex. 131.)

***United States' Response*:** The United States does not dispute that the above was testified to by Ms. Homer. *But see* United States' response to Paragraph 57 above (noting that in only five out of 23 instances when a state implemented a MAC program did the state also increase its dispensing fee around the same time, with an additional two states *lowering* their dispensing fee; the average change in the dispensing fees among these 23 states was just nine cents).

Defendants' Statement [59](n): In response to threats by chain pharmacies in 2002 that they would discontinue participation in Medicaid, Delaware abandoned a prior proposal to more significantly discount AWP in its reimbursement formula in favor of a lesser discount. Delaware's Cynthia Denemark testified the lesser discount was sought to avoid an "access [to care] issue." (12/9/2008 Denemark Dep. at 150:17-153:17, Ex. 22.)

***United States' Response*:** The United States does not dispute that the above was testified to by Ms. Denemark. Defendants' citation, however, is selective, incomplete, and misleading, and therefore the United States disputes the implied import of Paragraph 59(h). The witness further testified that there were "sufficient providers" who were willing to participate given the reimbursement such that there was compliance with federal regulations. (12/10/2008 Denemark Dep., at 366:5-366:11, Henderson Reply Ex. 11.)

Defendants' Statement [59](o): Oregon Medicaid has historically included a mail order component to its pharmacy program which allows Medicaid beneficiaries to order drugs by mail instead of by visiting a retail pharmacy. (12/16/2008 Anderson Dep. at 129:17-131:2, Ex. 132.) Prior to 2003, Oregon Medicaid reimbursed vendors dispensing drugs to beneficiaries via the mail order program at the same rates as traditional retail

pharmacies. In 2003, Oregon Medicaid solicited competitive bids for vendors wishing to run Oregon Medicaid's mail order program. (*Id*.) Vendors submitted bids with reimbursement proposals of up to AWP - 60%. (*Id*. at 135:19-137:4.) Oregon Medicaid admitted that it could have reduced traditional retail pharmacy reimbursement levels to such a large discount off of AWP, but that there "were political decisions" not to do so. (*Id*. at 141:18-142:8.)

***United States' Response*:** The United States does not dispute that the above was testified to by Mr. Anderson. Defendants' citation, however, is selective, incomplete, and misleading, and therefore the United States disputes the implied import of Paragraph 59(o) insofar it suggests that Oregon approved of falsely inflated price reporting. Both Mr Anderson and Kathy Ketchum testified that Oregon always reimbursed based upon a lower of methodology.

Q. So just as an overview: It appears that during the majority of the 1990s and through most of 2001, Oregon Medicaid defined its EAC for retail pharmacies as the lower of DP or AWP minus 11 percent; correct?
SCHNEIDER THOMAS: Objection, form.
A. THE WITNESS: My understanding of Medicaid is that we have always paid the lower of anything, whether they did the bill -- whatever was the lowest amount. If it was a federal upper limit, if there was -- if they billed less, if our AWP was less, that's what it was going to pay.

(12/16/08 Anderson Dep., at 63:12-64:2, Henderson Reply Ex. 59.)

Q. And at this time, Oregon Medicaid believed that its estimated acquisition cost was AWP minus 14 percent; correct?
MS. SCHNEIDER THOMAS: Objection, form.
A. THE WITNESS: AWP minus 14 percent is one option. There were more options in the algorithm; so EAC, or estimated acquisition cost, has to be SMAC, FUL, AWP minus 14 percent, usual and customary, billed amount.

(12/15/08 Ketchum Dep., at 105:16-106:2, Henderson Reply Ex. 60.)

Defendants' Statement [59](p): As of 2002, Rhode Island Medicaid had information that actual acquisition cost for generic drugs was on average AWP – 65.93% and WAC –

30.55%, but Rhode Island continued to reimburse providers at a rate of WAC + 5% for at least four more years. Rhode Island's 30(b)(6) representatives testified:

> Q. And do you recall we looked at page 7 of this report which relates that the OIG estimated that the invoice price for generic drugs was a national average of 30.55 percent below WAC rather than it being higher, and therefore perhaps supporting that a percentage be added to WAC and the results of their review, quote, show that WAC was not a true wholesale acquisition price and was significantly higher than the actual acquisition costs for generic drugs. Is it fair to say that as of 2002 Rhode Island Medicaid was on notice that WAC was significantly higher than the actual acquisition costs for generic drugs?
>
> * * *
>
> THE WITNESS: Yes.
>
> * * *
>
> Q. So is it fair to say that in 2002 Rhode Island Medicaid was on notice from OIG that WAC could differ from actual acquisition cost to a magnitude of up to 30.55 percent?
>
> * * *
>
> BY MS. RANKIN:
> Q. As stated in this report?
>
> * * *
>
> THE WITNESS: Yes.

(Ex. 133 (Roxane Rhode Island Ex. 12); 12/4/2008 Avarista Dep. at 230:17-232:11, Ex. 81.) When Rhode Island amended its definition of EAC, it moved from WAC + 5% to WAC. (12/3/2008 Young Dep. at 165:2-20, Ex. 134.)

***United States' Response*:** The United States does not dispute that the above was testified to by Ms. Avarista. However, the witness also testified that the cited OIG report did not survey

Rhode Island, provided WAC data from only one wholesaler, and that Rhode Island believed WAC was the best estimate they had of an average or "representation" of what pharmacies paid:

> Q. And does 1990 also the point at which you understood that pharmacies typically purchase drug products at prices much less than AWP?
>
> * * *
>
> THE WITNESS: Okay. We knew that it was not what they purchased it at. Didn't know how much it wasn't, but we know that it wasn't exactly.

(12/4/2008 Avarista Dep., at 120:21 - 121:9, Henderson Reply Ex. 42.)

> Q. And so the decision was made by Rhode Island Medicaid not to use actual acquisition cost as the basis, as the ingredient cost reimbursement basis in favor of WAC, a WAC-based methodology; is that right?
>
> * * *
>
> THE WITNESS: Actual acquisition cost varies between pharmacies, so the Wholesale Acquisition Costs was more of a general average of all the pharmacies because they all cannot purchase at the same price. What actual for one may be a lot less for another or more for another. So to use the actual acquisition cost, which would be very difficult to obtain, would not necessarily be equal for everybody. So the Wholesale Acquisition Cost was an average of all the companies, so it would be more easily to, if that was available to us and it would be more reflective of the general price.
>
> BY MS. RANKIN:
>
> Q. But you clearly had actual acquisition cost available to you in Exhibit B for some drugs. Did you make any effort to incorporate those actual acquisition costs into the reimbursement algorithm for those drugs?
>
> A. No.
>
> Q. Why not?
>
> A. That was only one – that was only one wholesaler and how that one wholesaler sold their drugs. Other wholesalers

> might sell it differently or direct prices differently or chain drug stores buy it differently. So using that actual acquisition cost could only be maybe for that particular manufacturer, wholesaler. Doesn't mean everybody's reflected that way. So the Wholesale Acquisition Cost gave us an average of what everybody was purchasing for.

(*Id.,* at 135:19 - 137:12)

Defendants' Statement [59](q): Larry Iversen testified that South Dakota Medicaid considered changing its estimated acquisition cost from AWP minus 10.5 percent, but decided not to because pharmacies complained that the current reimbursement plan was just covering their costs. (12/15/2008 Iversen Dep. at 59:2:61:12, Ex. 86.)

United States' Response: Undisputed. However, the United States disputes any assertion that the evidence indicates an intent to pay inflated EAC reimbursements or allow manufacturers to control the state's reimbursement amounts. To the contrary, it merely indicates that South Dakota sought to cover pharmacy provider costs. Mr. Iverson further testified that South Dakota sought to reimburse in accordance with the federal definition of "estimated acquisition cost":

> Q. (BY MS ACTON) So if you look at the first – the definition of estimated acquisition cost under Section 447.301; do you see that?
> A. Yes.
> Q. Can you read that quietly to yourself right now and tell me when you are done.
> A. Okay.
> Q. In using AWPs in your reimbursement methodology, specifically in determining the estimated acquisition cost, has the Department of Social Services endeavored to determine the estimated acquisition cost in accordance with that definition in the federal regulation that you are looking at?
> A. Yes.
> MS. RAMSEY: Objection to form.

(12/15/08 Iversen Dep., at 161:3-162:22, Henderson Reply Ex.38.)

Defendants' Statement [59](r): In 1998 and again in 2001, Arkansas obtained results of a Myers & Stauffer survey which revealed large spreads between AWP and AAC

pricing. (12/10/2008 Bridges Dep. at 206:21-207:18, Ex. 109.) Because of the 1998 Myers & Stauffer survey, Arkansas knew that some drugs could be purchased by pharmacies at rates as high as AWP-90%. (*Id*. at 287:13-17.) Based on the 2001 Myers & Stauffer survey, the state was aware that the AAC for drugs reimbursed under a MAC calculation was AWP-82%, compared to Arkansas' reimbursement rate of AWP-10.5%. (*Id*. at 294:3-297:8.) That same report also showed that average spreads between AWP and AAC for ipratropium bromide was AWP-70%. (*Id*. 329:20-332:19.) Despite the Myers & Stauffer reports and to address provider concerns, the state adopted a reimbursement rate of AWP-20% for generic drugs. (*Id*. at 306:20-307:12.)

***United States' Response*:** Disputed. Arkansas has reduced payment for drug ingredient costs several times during the relevant time period, and the testimony of the Arkansas Medicaid representative cited by defendants does not state either that its efforts were "curbed or defeated by political pressure from pharmacist and provider groups or that state decision-makers did not believe reductions in ingredient cost were appropriate or warranted." The Arkansas Medicaid representative further testified that if Arkansas received accurate AWPs, it would be much easier to estimate acquisition cost.

Q. Why wouldn't Arkansas' Medicaid Program adopt a definition of estimated acquisition cost for generic drugs of AWP minus 40 percent?
A. If we knew that the AWPs that were being provided to us were accurate, then we could have an accurate percent off of AWP, but I mean, based on this, we're -- again, this is an average. Not every pharmacy might be able to accommodate that average. So we just can't do that.
Q. So on average, pharmacies are receiving a 22.5 percent net margin for generic drugs reimbursed by Arkansas' Medicaid Program?
MS. MOSLEY-SIMS: Objection.
A. Again, I'm not meaning to sound difficult, but what I'm -- what I'm going to say is the State should not have to be the ones to police this issue. If the manufacturers would provide a more accurate AWP, then we wouldn't have to be worrying about, you know, what pharmacy received what price and what percentage off. So then it would be a much easier

> process. So why we don't do it, I can't answer that question directly.

(12/10/08 Bridges Dep., at 251:18-253:22, Henderson Reply Ex. 31.)

Defendants' Statement [59](s): Pharmacy associations played an important role in setting reimbursement rates in Tennessee and, in one instance, Tennessee Medicaid's attempt to implement a most favored nation policy with respect to usual and customary pricing was met with strong opposition from NACDS and abandoned. (Ex. 135 (Abbott Ex. 579); 3/12/2008 Sullivan Dep. at 167:16-170:2, Ex. 1.)

***United States' Response*:** Disputed. The evidence cited by defendants indicates that Tennessee's attempt to implement a most favored nation policy was abandoned because HCFA agreed with NACDS that the proposed change to the state's reimbursement methodology was in violation of a federal statutory moratorium on reductions in reimbursement limits (OBRA 1990, Pub. L. 101-239, Sec. 4401(a)(3) (adding 42 U.S.C. § 1396r-8(e)).

Defendants' Statement [59](t): OIG's Ben Jackson, who worked with the states throughout the 1990s relating to OIG's audits of the difference between AWP and invoice costs, testified:

> Q. And what is your view, Mr. Jackson, as someone who has been very involved in this issue in the 1990s about why it is that the state Medicaid programs did not change their reimbursement formulas to match or get closer to your findings?
> A. I think I've answered that question already. I mean, I think you've got state legislatures you've got to contend with. You've got lobby groups. You've got state budgets. I mean, there's a lot of things that could play into that.

(12/12/2008 Jackson Dep. 392:6-17, Ex. 37.)

United States' Response: The United States disputes the admissibility of the testimony as speculative.

I. CMS "Decision Memoranda"

60. On or around 2001 to 2002, the CMS Medicaid Pharmacy Team drafted a document titled "Review of Medicaid Drug State Plan Amendments." (Ex. 136 (Abbott Ex. 328.) That document contained the following language:

> Recently issued OIG reports indicated that the actual acquisition cost of brand name prescription drug products nationally is an average of AWP less 21.84 percent. Recent discussions with the OIG indicate that they will further refine this number to differentiate it between those single source (brand name drugs) without generic competition and those with innovator multiple source (brand name drugs) with generic competition. The ala indicates that the single source drugs will likely show an average discount of around 17% and the innovator multiple source drugs of around 24%. The OIG also studied generic drug discounts and found that the actual acquisition cost of generic prescription drug products nationally is an average of AWP less 65.93 percent.
>
> * * *
>
> ANALYSIS
>
> In recent months there has been an increase in SPAs proposing to change the reimbursement methodology (a listing of these SPAs is attached). Where there are surveys of costs, the findings generally show that these State's reimbursement could have been reduced by a percentage greater than the proposed AWP discount levels. The lesser level of discount is generally the result of negotiations that occur between the state and pharmacy representatives after the survey results are known. In other cases, the states legislature have responded to the escalating costs of Medicaid drugs by enacting legislation that increases the discount in the ingredient cost or the dispensing fee of these drugs. Legislation usually does not address why these rates are the best estimates or are reasonable.
>
> It is proving increasingly difficult to require the states to establish payment rates in adherence to regulatory requirements. Accordingly, we believe an analysis and an acceptance of other factors states are now using to establish payment rates should be considered in looking at the EAC and the dispensing fee.
>
> We think that the first part of our review should be continuing to rely on the existing review criteria (i.e. survey and rates in other states). For EAC, we would continue to look to surrounding states or because we now think that payment rates vary little nationwide, to a

> nationwide average. We think it is also helpful to strongly consider approval where the direction of the state's proposed level of reimbursement represents a program savings that does not appear to affect pharmacy participation. Finally, we think. EAC needs to include a broader measure of factors that would result in a state agency's best estimate. We could consider the actions of the legislature or negotiations that result in a lower payment rate, even if that rate may differ from other documentation, such as a state survey.
>
> Because the requirements to set dispensing fees are less specific, we would continue to allow states greater flexibility here. For instance, we would permit states to reduce these fees not only to reflect lower costs; but also to permit states to increase them to encourage other program savings measure, such as allowing a higher dispensing fee for the use of generic drugs.
>
> Apart from that, we think a longer-range look at the OIG and state studies as well as a reevaluation of current regulations are in order. If, in fact, there needs to be another basis, such as nationwide surveys that can establish these rates, we need to look at the feasibility and impact of doing so.

(*Id*.)

United States' Response: The United States does not dispute the statement except as to materiality. The United States further contends that the observation in the memorandum that "[i]t is proving increasingly difficult to require the states to establish payment rates in adherence to regulatory requirements" is a direct result of false price reporting of defendants and other drug manufacturers.

61. On October 22, 2002, CMS Administrator Tom Scully signed a decision memorandum on the subject of "Review of Medicaid Drug State Plan Amendments." (Ex. 137 (HHD830-000001-04).) That memorandum included the following language:

> We are writing to seek your approval for criteria to be used for reviewing state plan amendments (SPAs) that seek to change the payment rates for drugs. There are no explicit statutory provisions for payment rates for Medicaid drugs. States are required to set rates in accordance with regulations at 42 CPR 447.301-333.

* * *

Recent OIG reports estimate the actual acquisition cost of brand name prescription drug products nationally to be, on average, the average wholesale price (AWP) less 21.8 percent. The OIG recently revised this number to differentiate it between those single source brand name drugs without generic competition and those innovator multiple source brand name drugs with generic competition. The OIG estimates that the single source brand name drugs cost, on average, AWP less 17.2 percent and the multiple source brand name drugs cost AWP less 24.4 percent. The OIG also studied generic drug discounts and found that the actual acquisition cost of generic prescription drug products nationally is, on average, AWP less 65.9 percent. Industry sources indicate that nationally, higher profit margins are obtained on generic prescription drug products. . . .

ANALYSIS

In recent months, there has been a significant increase in the number of SPAs proposed which would change the reimbursement methodology. State cost surveys have generally showed that state reimbursement could be reduced by a percentage greater than the proposed AWP discount level. The discount level has usually been reduced as the result of negotiations between the state and pharmacy representatives after the survey-results are known. In other cases, the state's legislature has responded to the escalating costs of Medicaid drugs by enacting legislation to increase the discount in the ingredient cost or decrease the dispensing fee. Legislation usually does not address the basis for the ingredient cost reduction or the reasonableness of the dispensing tee,

It is proving increasingly difficult to require states to provide statistical data to support their proposed payment rates. In addition, we believe that other sources of information and other factors can be used to evaluate the appropriateness of payment rates.

As an alternative to requiring states to provide surveys or statistical data to support their proposed rates, we would ask states to compare their proposed rates to those of other states. For EACs, we would broaden our comparisons from surrounding states to all states because the market for drugs is national. In order to provide states with current payment rates of other states, we will maintain a list of each state's current EACs and dispensing fees on the CMS Web

> page. (For dispensing fees, we will put more weight on other states in the region, as these cost may differ by geographic cost differentials.) In short, we will look favorably on proposals to reduce reimbursement when there is a basis to conclude that the reduction will not affect pharmacy participation.
> Finally, we will approve rates set by the legislature or through negotiations, even if the rate differs from that suggested by other documentation, such as the rates of other states or from a state survey.
>
> Because the regulations on dispensing fees are less specific (i.e., the standard is "reasonableness"), we would continue to allow States greater flexibility here. For instance, in addition to allowing states to reduce these fees to reflect lower costs, we would also permit states to increase or vary their rates in order to provide incentives to pharmacists to dispense less costly drugs, such as by allowing a higher dispensing fee for dispensing generic drugs.

(*Id.*)

United States' Response: : The United States does not dispute the statement except as to materiality. The United States further contends that the observation in the memorandum that "[i]t is proving increasingly difficult to require the states to establish payment rates in adherence to regulatory requirements" is a direct result of false price reporting of defendants and other drug manufacturers.

62. With respect to the CMS "Review of Medicaid Drug State Plan Amendments" decision memorandum, CMS's Dierdre Duzor testified:

> Q. Ms. Duzor, I've handed you a copy of what we've marked previously as Exhibit Abbott 328, a document entitled Review of Medicaid Drug State Plan Amendments. I ask you to take some time and look at that document.
> A. Okay. (Reading.)
> Q. Ms. Duzor, have you had a chance to look at that document?
> A. Yes, I have.
> Q. Can you tell us what this document is?
> A. This document –
> Q. Let me strike that. Are you familiar with this document first?

A. Yes. I recall the document.
Q. Can you tell us what it is?
A. I believe it is a draft of a decision memo seeking guidance from policymakers in CMS on approaches to reviewing state plan amendments that were proposing to revise either the ingredient cost payment for drugs or the dispensing fees.
Q. What is a decision memo?
A. A decision memo is an issue paper with recommendations to take to policy decision makers. Options and recommendations generally.

(10/30/2007 Duzor Dep. at 176:16-177:17, Ex. 38.)

* * *

Q. What did you believe on a national level was the rate of discounts from AWP for generic drugs?
MS. MARTINEZ: Objection to form.
A. We knew that for generic drugs that AWP minus 13 was a generous payment based upon the IG's findings.

(*Id*. at 191:19-192:3.)

United States' Response: Undisputed, except that Ms. Duzor was testifying about the draft memorandum identified in Paragraph 60 above, not the signed document identified in Paragraph 61.

63. Ms. Duzor acknowledged that HCFA and CMS gives state legislatures deference when reviewing state plan amendments. (3/26/08 Duzor Dep. at 782, Ex. 54.) Duzor testified that if a state told CMS that its legislature had authorized a state plan amendment, that alone was a sufficient reason for CMS to approve the change. In those cases, CMS would not inquire into exactly why the legislature did what it did or the process it followed. (Id. at 589-90.) Duzor stated that she was aware of "pretty intense lobbying in state legislatures" by pharmacies and their representatives on the topic of drug reimbursement. (2/27/08 Duzor Dep. at 410-11, Ex. 82.) Duzor surmised that Medicaid officials preferred to allow the existence of a spread due to lobbying and political pressures that make it difficult for states to reduce reimbursement:

Q. Do you have any understanding of why these state Medicaid officials prefer to submit reimbursement formulas for reimbursement costs that allow the existence of the spread?
A. THE WITNESS: I believe that they, like us, are trying to reduce the amount of the reimbursement, but there are

economic and political realities in a state that make it difficult.

* * *

Q. What are those economic and political realities?
A. That the pharmacies that are benefitting from the spread are politically powerful and oppose any reductions.

* * *

Q. Well, is it your understanding that the state pharmacy directors are generally aware about these -- of these OIG reports?
A. Oh, yes.

* * *

A. THE WITNESS: I do believe they are. We have sent them to state Medicaid directors. . . .
Q. So then it's fair to say that the state officials responsible for state Medicaid policy that deal with the legislatures are aware of these 40 percent and potentially higher spreads on generic drugs, correct?

* * *

A. THE WITNESS: I believe that the state pharmacy directors are, and probably most state Medicaid directors are.

* * *

Q. Why do you believe the state Medicaid agency chooses to recommend plans that allow spreads to be paid for generic drugs –

* * *

Q. -- on the order of 40 percent or higher?

* * *

A. THE WITNESS: Because they have to have the approval in their executive branch and frequently in their legislative branch to change the way they pay pharmacists. And they don't get support for dramatically lower reimbursement rate.

(3/26/08 Duzor Dep. at 651-55, Ex. 54.)

United States' Response: In general the United States does not dispute that the above testimony was given. Some of defendants' characterizations are inaccurate, but not materially so. The United States does dispute the admissibility and materiality of the testimony.

64. Ms. Duzor further testified that, although OIG reports showed discounts of over 60 percent below AWP for generic drugs, CMS continued to approve state plan amendments that allowed reimbursement at AWP minus 15 or AWP minus 20 "[b]ecause they're moving in the right direction. They're reducing pharmacy reimbursement and saving the states and the federal government money by doing so." (*Id*. at 646:18-647:9.) CMS approved these state plans even though it was aware for some time based on OIG reports "that the pharmacies [were] making money on the difference between what they're acquiring the drug for and what they're reimbursing it at in the case of generics." (*Id*. at 646-47.)

United States' Response: Disputed to the extent that defendants characterize Ms. Duzor's testimony as describing historic practice. Ms. Duzor was testifying in the present tense, concerning the CMS practice at the time of the deposition (March 2008).

65. Regarding how states are currently reimbursing for generic products, Ms. Duzor stated:

A. Providers are being paid based on a formula that is a discount off of AWP or a small add-on to WAC. I mean, the idea that you're saying that states are paying them the spread, I don't think that we view it or that states view it in that way. Their payment methodology has that result.
Q. Okay. And you're aware of that result today, correct?
A. Yes.
Q. And so CMS is not being fooled about anything when it comes to the fact that they are paying a spread for generic drugs today?
. . .

A. There was testimony before congressional committees. There was the enactment of the DRA. All of that was in recognition of the fact that the AWPs were not good estimates of real cost and that Medicaid is paying too much for drugs.

(2/27/08 Duzor Dep. at 330-32, Ex. 82.)

* * *

Q. And you know that the state Medicaid plans reimbursement methodologies now are reimbursing at rates nowhere close to that amount; isn't that right?

. . .

A. The state of Washington is doing pretty well at AWP minus 50. But they are the exception for generics.

Q. And that's only for drugs that have five or more labelers or manufacturers, correct?

A. Yes. That's true.

Q. Not for all generic drugs?

A. Right.

Q. And they're the exception.

A. Yes, they are.

(10/30/07 Duzor Dep. at 238, Ex. 38.)

United States' Response: Undisputed.

66. Kim Howell began working for CMS as a senior drug policy analyst in September 2000. (4/22/08 Howell Dep. at 67-68, Ex. 138.) Howell was a medical care programs supervisor for Maryland's Medicaid programs from 1994 to 2000. (*Id.* at 31-32.) Howell explained that higher officials at CMS, such as Larry Reed, could approve state plans even if the state's supporting documentation did not justify the amendment:

Q. And if you had not received that documentation to support the reimbursement methodology as the best estimate, yet still approved it, then CMS didn't do its job?

* * *

A. No. Then the recommendation from the analyst would have went to Larry Reed as to this is what the state is proposing, this is what the state has provided to us. And then it was

Larry Reed's responsibility to take it to the authorities above him to provide them with the issue and they would make the decision.

Q. So if there was going to be an exception to the rule it has to get done above you?

* * *

A. Exactly.

Q. And we saw that in Wisconsin such an exception happened?

* * *

A. The state plan was approved.

(*Id*. at 248 249.) Howell explained that because of the disparity between the proposed reimbursement levels in the state plan amendments submitted to CMS and the data available to CMS regarding drug costs, she sought guidance from higher-ups within HCFA:

Q And the state plans that were being submitted to you, the state plan amendments that were being submitted to you, were not in your view setting forth reimbursement methodologies that were consistent with the data that you had; is that fair to say?

A. Yes. That's correct.

Q. And because of that, the difference between what was being submitted and the regulations, you wanted to get approval from someone higher than you?

A. It's not that we wanted. We needed to have guidance from the management of CMS.

(*Id*. at 275-276.) Ms. Howell drafted the first draft of the "Review of Medicaid Drug State Plan Amendments" document. (Id. at 270-71; Ex. 136 (Abbott Ex. 328).) With respect to that document, Ms. Howell testified:

Q. If you would go to the second page of the decision memo, you wrote there at the top "Analysis: In recent months there has been an increase in SPAs" that means state plan amendments?

A. State plan amendments.

Q. "Proposing to change the reimbursement methodology (a listing of these SPAs is attached). Where there are surveys of cost the findings generally show that these state's

reimbursement could have been reduced by a percentage greater than the proposed AWP discount levels." And that's something that you had seen personally?

A. This is the problem that the entire team was seeing. So it's just not based on the state plans that I personally was reviewing. This was what the other analysts, the problems they were seeing also.

(4/22/08 Howell Dep. at 277 278, Ex. 138.)

United States' Response: Undisputed except as follows: Disputed with respect to the characterization of Kim Howell's testimony regarding Larry Reed's authority. As the quoted testimony indicates, Ms. Howell testified that Mr. Reed would have to seek higher authority within CMS for approval of state plans if the analyst believed the state had not provided adequate support for the amendment. The United States also disputes the characterization of Ms. Howell's testimony regarding "the data available to CMS regarding drug costs." Ms. Howell was only testifying regarding the data submitted by states when seeking state plan amendments, not drug cost data in general.

Q. Can you tell us what this document is?

A. This was an internal document to discuss an issue that was becoming a problem regarding state plan amendments where states were beginning to submit state plans where the documentation did not support what the state was proposing. And because it had been becoming a repeated concern we wanted to get guidance from Dennis Smith and above us to determine how to address those particular state plan amendments.

(9/26/07 Reed Dep., at 270:19 - 271:6, Henderson Reply Ex. 24.)

67. With regard to how CMS responded to OIG's reports on the differences between AWP and invoice costs for drugs, OIG's Ben Jackson testified:

> Q. I believe you testified that in conversations with legislators and their staffs you indicated that you were at times critical of CMS, right?
>
> * * *
>
> A. I think we felt as an agency that CMS could have done more with the states, yes.

(12/12/2008 Jackson Dep. at 388:7-10, 18-19, Ex. 37.)

United States' Response: Undisputed, except that the United States objects to the evidence as inadmissible.

J. The States' Responses To The DOJ AWPs

68. On April 21, 1999, Congressman Pete Stark of the U.S. House of Representatives Committee on Ways and Means sent a letter to HCFA Administrator Nancy-Ann Min DeParle that included the following statement:

> I urge you to take a simple and easy step to counteract an ongoing fraudulent practice by some pharmaceutical manufacturers that is costing Medicare and Medicaid hundreds of millions of dollars in excessive reimbursement payments. It is my understanding that HCFA and various antifraud units of the government have been working with a company known as First Data Bank to make available more accurate drug pricing information. If my understanding is correct, I request that you immediately issue written guidance to the States' Medicaid Programs approving their use of First Data Bank's agreed reporting of more accurate prices in calculating reimbursement amounts for certain injection, infusion and inhalation drugs and biologicals. I also request that you take similar action to insure that the Medicare carriers have access to and use the more accurate First Data Bank prices for the drugs and biologicals in question.

(Ex. 139 (Abbott Ex. 136).)

On April 26, 1999, DOJ's T. Reed Stephens faxed Mr. Stark's letter to Mary E. Riordan, Office of Counsel to the Inspector General, with the following note: "Letter from Congressman Stark to HCFA administrator last week. Stark is not aware of the qui tam but apparently is aware of our contacts with First Databank." (*Id*. at 2.) On April 27, 1999, Ms. Riordan faxed Mr. Stark's April 21, 1999 letter to Bob Niemann, CMS Drug Payment

Policy Analyst (Medicare) and Larry Reed, Technical Director, CMS Medicaid Division of Pharmacy. (*Id*. at 1.)

United States' Response: Undisputed. Further answering, Mr. Stark's letter to Ms. DeParle included the following language:

> We have working together for a long time to make sure that the amounts paid for prescription drugs by the Medicare, Medicaid and other Federally funded programs, are not excessive, particularly in light of the applicable laws and regulations which require that reimbursement be reasonable and based upon the acquisition cost of the drug.

(Defendants' Amended Exhibit 139).

69. On February 16, 2000, Patrick E. Lupenetti [sic], a member of the NAMFCU Drug Pricing Team, sent a letter to Medicaid Pharmacy Directors concerning a national investigation by State and federal agencies regarding drug pricing and an effort to work with First DataBank to improve the accuracy and validity of pricing information provided for a limited number of medications – generally infusion, inhalation, and injectable products. (Ex. 140 (Abbott Ex. 137).) The letter indicated that "the substance of this proposal has already been outlined to State Pharmacy Directors, particularly at your July 1999 national conference, in a presentation in which Assistant United States Attorney Reed Stephens, HHS-OIG Associate General Counsel Mary Riordan, Maryland MFCU Director Carolyn McElroy and most State Pharmacy Directors participated." (*Id*.)

United States' Response: The United States does not dispute that defendants have accurately, but selectively, summarized and quoted a portion of the letter sent by Patrick E. Lupinetti on February 16, 2000. Further answering, the letter noted that "a current national investigation by State and federal agencies revealed a pattern of misrepresentation by some drug manufacturers of the average wholesale prices and wholesale acquisition costs of certain of their products" resulting in "substantial" overpayments.

70. On May 1, 2000, First Databank provided new average wholesale prices (hereafter, the "DOJ AWPs") for approximately 400 NDCs. (Ex. 141 (Abbott Ex. 184).) The 400 NDCs represented 51 injectable, infusion, and inhalation drugs, including Abbott's vancomycin, dextrose, and sodium chloride. (*Id*.)

United States' Response: Undisputed.

71. On September 2001, the Office of Inspector published a report, titled "Medicaid's Use of Revised Wholesale Prices" (OEI-03-01-00010), that analyzed whether the State Medicaid programs were utilizing the DOJ AWPs. (Ex. 142 (Abbott Ex. 95.) The report contained a chart that purported to show whether each state "Uses Revised Prices for Pharmacy Drugs," "Uses Revised Prices for Physician Drugs," and "Subtracts Discount for Revised Price." (Id. at 10-11.) The chart indicated that 20 states did not use the DOJ AWPs for any Pharmacy Drugs, and another eight Medicaid programs (Alabama, D.C., Idaho, Kansas, Ohio, Oregon, Texas, and Wisconsin) that did not use the DOJ AWPs for certain drugs. (*Id*.)

United States' Response: The United States does not dispute that in September 2001, OIG published a report titled *Medicaid's Use of Revised Wholesale Prices*, and that defendants have selectively described information contained in the report. The United States disputes, however, any assertion or inference that state Medicaid programs which did not use the "DOJ AWPs" intended make inflated payments based on inaccurate pricing information reported by drug manufacturers. The referenced report indicates that states articulated various reasons for not using the "DOJ AWPs" including concerns that DOJ and NAMFCU did not plan to "provide updated pricing information" and "that providers and manufacturers would find ways to circumvent the new prices" by obtaining new drug codes for their products. (Defendants' Ex. 142, at 6, 7).

Several state Medicaid witnesses indicated that their Medicaid programs did not implement the DOJ AWPs because it was difficult or impractical to alter their reimbursement system for only 400 NDCs. (*See*, *e.g.*, 12/11/2008 Bridges (Arkansas), at 506:6 - 507:6, Henderson Reply Ex. 99; 12/2/2008 Cheloha (Nebraska), at 257:1 - 257:16, Henderson Reply Ex. 100). Other state Medicaid witnesses testified that their programs did not implement the DOJ AWPs due to concerns that they could not be updated. For example, Jeff Buska, a representative of the Montana Medicaid program, testified as follows:

Q. Did there come a ponit in time when Montana Medicaid stopped using the DOJ AWPs?
A. Yes, I do recall that we did stop using it.
Q. Do you know roughly when that was?
A. I don't know exactly when.
Q. Why did Montana Medicaid stop using those AWPs?
A. Because the AWP pricing was not being updated by First Data Bank, and my recollection is that the drug manufacturers wouldn't respond to their surveys.

(12/14/2005 Buska Dep. (Montana), at 311:21 - 312:9, Henderson Reply Ex. 61; *see also* 3/25/2008 Kramer Dep. (Michigan), at 208:5 - 209:5, Henderson Reply Ex. 2.)

72. In its response to a draft of OIG's report on Medicaid's Use of Revised Wholesale Prices, CMS included the following statement:

> The OIG concludes that because most states base their reimbursement for drugs on AWPs, inflated AWPs have "caused Medicaid to overpay for these products." (See pages ii (Conclusion) and 9 (first paragraph.)). Since the regulations and relevant state plans authorize payment for drugs based on AWPs. regardless of whether those prices are inflated, we have concerns with the statement that states and Medicaid have "overpaid" for drugs. We therefore recommend that the sentences on pages ii (penultimate paragraph, second sentence) and 9 (first paragraph, second sentence) be deleted.

(*Id.*). OIG deleted the language referenced in CMS's comment in the final draft of its report.

United States' Response: The United States does not dispute that defendants accurately, but selectively, quoted excerpts from CMS' comments to the referenced report. The United States disputes, however, any implication that CMS was opining on the legality or propriety of defendants' conduct. On the contrary, federal reports cited by defendants regularly indicate disapproval of AWPs that exceeded providers' actual acquisition costs. For example, in comments made to a January 2001 OIG report titled *Medicare Reimbursement of Prescription Drugs*, HCFA

described the then "current AWP-based reimbursement method" as one that "cheats taxpayers." (Henderson Reply Ex. 62) HCFA also noted its belief that "payment of inflated drug prices is an inappropriate way to compensate practitioners and suppliers for inadequate reimbursement of other practice costs." *Id.*

Further responding, when Larry Reed (a current CMS employee) was asked about the language quoted in Paragraph 72, he testified as follows:

> A. Again, I'm only skim reading pretty much along with you. But it appears to be that the OIG's problem – or that OIG's concern, if you will, isn't necessarily overpayments but the use of AWP. And CMS's response is AWP, even if you consider it to be inflated, still is used by the agencies. Those agencies may discount that AWP. And the simple use of AWP doesn't necessarily mean that Medicaid has overpaid for those drugs.
> Q. Mr. Reed, do you recall discussions within CMS about the topic of whether or not payments based upon inflated AWPs were resulting in overpayments?
> A. I think certainly there was interest in looking at AWPs to look at how -- what they represented, what they continued to represent. And again, just as something that we learned more about over time, and even ultimately what other measures we might choose. And I think kind of the result of that concern is eventually the use of AMPs in the Deficit Reduction Act, for example, for the FULs program and for those to be made publicly available.

(3/20/2008 Reed Dep., at 193:12 - 194:10, Henderson Reply Ex. 63.)

73. In its project to assist Dr. Duggan with information on how the state Medicaid programs paid providers for dispensing drugs, Myers & Stauffer also analyzed the states' use of the DOJ AWPs. Myers and Stauffer found five states (Delaware, Idaho, Indiana, Oklahoma, and Pennsylvania) that OIG's report indicated were utilizing the DOJ AWPs, but for which they were unable to verify use of the DOJ AWPs, and another two states (Illinois and Montana) which eventually stopped using the DOJ AWPs. (Ex. 143.) OIG's report identified four states (Kentucky, Minnesota, Missouri, and North Dakota) that "used the DOJ AWPs at one time, but no longer do[] so." (Ex. 142 at 10-11 (Abbott Ex. 95).)

United States' Response: The United States partially disputes paragraph, in that it relies on "draft" summaries of state reimbursement methodologies that Myers and Stauffer subsequently refined. and which the United States filed in support of its motion for summary judgment. (Declaration of Myers and Stauffer LC, Henderson Common Ex. 24 (MD #6310, Sub. #308)). A slightly revised and more accurate statement of the subject is set forth in paragraph 21 of the Declaration of Myers and Stauffer, which is reproduced here:

> Twenty-nine (29) states also have used the "DOJ Price" plus a dispensing fee as part of their reimbursement methodology. The term "DOJ Price" refers to prices provided in 2000 by the DOJ and the National Association of Medicaid Fraud Control Units and published by First DataBank. For a few of these twenty-nine (29) states, the DOJ prices were used for only a short period of time. For another three (3) states, a 2001 report of the HHS Office of Inspector General[2] identified the state as using the DOJ prices, but Myers and Stauffer was unable to confirm this with state agency staff. All of the states that used the DOJ Prices used them as part of their "lower of" reimbursement methodology.

(Henderson Common Ex. 24, ¶ 21.)

74. Missouri is one of a number of states that implemented the DOJ AWPs, but later reversed its decision. In June of 2002, Missouri's Office of State Auditor wrote a performance audit titled "Cost Containment for State Drug Expenditures." (Ex. 144.) The report contained a discussion of Missouri's use of the DOJ AWPs, including the following language:

> Within 2 months of Department of Justice notice of the more accurate average wholesale prices, Utah officials began using the lower drug prices with new dispensing fees. With the help of infusion specialty providers, Utah officials categorized the 437 drugs into 5 groups appropriate to the preparation and overhead costs for the product. The new dispensing fees set up for drugs in 4 of the 5 categories ranged from $8.90 to $33.90 per prescription.

[2] HHS OIG, *Medicaid's Use of Revised Average Wholesale Prices*, OEI-03-01-00010, September 2001. (Footnote in original.)

> Missouri officials initially implemented the more accurate prices for provider reimbursement using the normal $4.09 dispensing fee, which was not designed to cover these drugs. Division officials reversed the decision after home infusion providers threatened to cease services due to insufficient dispensing fees. Provider personnel admitted the former reimbursement rates exceeded their product acquisition costs, but they used the excess reimbursement to offset the higher dispensing costs of home infusion drugs. Division officials indicated they plan to use these lower prices again after determining adequate compensation for home infusion services. While no implementation date has been set, the Division Director stated the necessary changes to implement these prices would be part of the division's fiscal year 2004 budget proposal.

(*Id*. at 9.)

***United States' Response*:** Disputed. The cited exhibit does not support defendants' assertion.

75. Similarly, California Medicaid did not adopt the DOJ AWPs. A document produced by California contains the following language regarding why California did not adopt the prices:

- Accepting these new AWP's as the basis for provider reimbursement in Medi-Cal is a serious policy consideration. This change would result in dramatic decreases in the reported AWP for approximately 400 drugs—decreases of as much as 80% in some cases. The new AWP reductions apply to drugs which are usually administered in physicians' offices or clinics. However, the same drugs are often administered at patients' homes via pharmacy dispensing and home health care administration."

- "The Department is concerned that providers affected by the new AWPs may discontinue serving FFS Medi-Cal patients if the new prices are implemented. If this occurs, patients would either not have access to these important drugs or patients would be directed to a hospital to obtain them."

- Department staff recently participated in a national teleconference on this subject involving other state Medicaid pharmacy programs. Many pharmacy program administrators

> indicated that they were not implementing the new AWPs at this time because of concerns over provider discontinuation and resultant patient access problems."
>
> - "We recommend that Medi-Cal not implement the new price reporting mechanism due to the serious impact on both the providers and beneficiaries."
>
> (Ex. 145 (Gorospe Ex. 14 (3/19/08 Dep).) California's Kevin Gorospe confirmed that California did not adopt the DOJ AWPs out of concerns over access. (3/19/08 Gorospe Dep. at 198:7-201:14, Ex. 20.)

United States' Response: The United States partly disputes this paragraph as incomplete.

Mr. Gorospe also testified as follows regarding the DOJ AWPs:

> Q. Do you have an understanding for the basic reason why the Department didn't implement Medicaid AWPs?
> A. Yes.
> Q. Can you describe some of those reasons?
> A. My recollection is that the -- the Department decided not to implement the AWPs at the time because it was concerned that the reimbursement would not change – in other words, the AWPs would not change over time as prices increased. Also, that there was a potential that if they – the prices were lower than acquisition costs to the pharmacies, that the pharmacies wouldn't want to dispense the products.
> Q. So you would agree that one of the concerns was access to – access to care for beneficiaries?
> MR. PAUL: Objection to form.
> A. THE WITNESS: Yes.

(9/22/08 Gorospe Dep. at 519:22-520:14, Henderson Reply 64) Responding further, *see supra* United States' Response to Paragraph 71.

76. CMS's Larry Reed testified about the DOJ AWP project:

> Q. Do you recall that starting in 1999 or thereabouts the Department of Justice began to discuss with HCFA and the states the possibility of using more accurate average wholesale prices that they had developed?
> MS. MARTINEZ: Objection, form.

A. No. I don't recall that type of effort, an overall effort to get a more accurate AWP.
Q. You don't recall anything about that effort at all?
A. No. There was a specific effort for a specific manufacturer, but I don't recall this effort.

(3/18/2008 Reed Dep. at 780:16-781:7, Ex. 146.)

United States' Response: Undisputed.

77. Susan Gaston, Health Insurance Specialist at CMS from 1991 to 2003, testified that the DOJ AWP effort was "the result of a litigation suit." (3/19/2008 Gaston Dep. 397:10-398:3, Ex. 147.)

United States' Response: The United States does not dispute that, in response to a question about who "spearheaded" the DOJ AWP effort, Ms. Gaston testified that she "thought it was the result of a litigation suit." Further answering, the joint effort by the National Association of Medicaid Fraud Control Units and the Department of Justice to collect accurate pricing data, including background information about that effort, was addressed in a HCFA Program Memorandum. (HCFA Program Mem. 00-86, Henderson Reply Ex. 65.)

78. Evidence indicates that some states believed that the "DOJ AWP effort" was an effort to redefine AWP. On June 22, 2000, Minnesota's Cody Wiberg sent an e-mail to the National Medicaid Pharmacy Administrators wherein he stated:

> While the legislators did not define AWP, we believe that their intent was to use "AWP" to mean a single estimate of wholesale price as published in a compendia such as Redbook or First DataBank. My understanding is that FDB is now publishing two sets of "AWPs" for the 428 drugs in question – one for Medicaid agencies and one for everything else. The fact that the legislators chose to estimate actual acquisition costs at AWP-9% indicates that they were aware that the single, published AWP was actually higher than the price for which most pharmacies could buy drug products. Had they known that AWP would be reduced to AAC, they would not have established a 9% discount off of AWP.
>
> * * *

> Some public and private third party payers have purposely kept the dispensing fee low precisely because there is a spread between AWP and AAC. In fact, when pharmacy organizations have sought an increase in dispensing fees, the AWP spread has been pointed out to legislators. It is true that ingredient reimbursement is supposed to be based on estimated acquisition cost. The ancillary costs of dispensing the drug are supposed to be accounted for by the dispensing fee. If the AWP spread disappears, the dispensing fee may have to be increased, especially for many of the 428 drugs currently in question. Many of these drugs require some type of compounding or other preparation.

(Ex. 148 (Abbott Ex. 492); see also Ex. 149 (Abbott Ex. 584).)

United States' Response: Disputed, on the ground that this statement relies on inadmissible hearsay. The document referenced is an out of court statement offered by Defendants for the truth of the matters stated therein. Further, the declarant had no apparent authority to speak on behalf anybody, much less "legislators." In addition, Mr. Wiberg is not competent to testify as to what legislators or "states" thought or intended. *See*, *e.g.*, *Thornburg v. Gingles*, 478 U.S. 30, 43 n. 7 (1986) ("We have repeatedly recognized that the authoritative source for legislative intent lies in the Committee Report...").

Further answering, Defendants' quotation from Mr. Wiberg's email is selective and incomplete. In the referenced email, Mr. Wiberg also wrote that "[t]here is no doubt in my mind that NAMFCU is correct when it points out that the spread between AWP and AAC is too large for many, even most of these drugs" and that "[i]n Minnesota, we believe that something should be done about the AWP spread." Defendants Ex. 148.

K. State MACs

79. State officials testified regarding the source of pricing information they used to establish MACs:

United States' Response: The United States does not dispute that various state MAC programs used methods that did not rely "exclusively" on the published prices for defendants' drugs. However, the United States disputes that the specifics of any State's MAC program are material to any issue presented in the summary judgment motions. *See generally* United States' Response to Dey's Statement of Facts, ¶ 35. The United States' theory of recovery and damages model are not based upon defendants' false price statements causing inflated MACs; rather, the United States asserts that defendants' false price representations caused EAC to be inflated, and thereby caused damages whenever the original reimbursement amount – whether based on EAC, MAC, FUL, or U&C – was higher than it would have been but for the inflated EAC. All or nearly all states would have based reimbursement on EAC had it resulted in a lower amount. (Henderson Common Ex. 24 (Knerr Decl.) ¶ 18, 19, 24.)

Responding further, the United States disputes any implication or assertion that it was feasible for states to institute MACs on every drug, or that it was feasible for states to base their reimbursement models on non-published pricing. As noted in paragraphs 23 and 24 of United States' Common Statement of Facts (Dkt. No. 6316, 312), state Medicaid officials testified that they required accurate, current and comprehensive pricing information to process millions of claims for reimbursement on many thousands of different products.

Defendants' Statement [79](a): Tennessee's H. Leo Sullivan testified:

> Q. Now where would you get the information that you would use in the MAC program regarding what pharmacists were—pharmacies were actually paying for drugs?
> A. My, my system was, was not very sophisticated or very scientific, but nonetheless believe it to have been very effective. What I did was, I knew I had a contact within the largest generic distributor in our area, and one of the

> most—one of the more popular. Again during this time that I, that I was setting MAC prices, rather than MCOs or PBMs, the, the best deal on generic weren't coming from, from big wholesalers. They were coming from generic distributors. So I had contacts within this one particular company who would tell me, who would first of all keep me apprized any time they, they were able to distribute new generic drugs, also give me information if, if there was some problem with an existing generic drug's availability, and also tell me and give—send me catalogs that they sent to the pharmacists and then tell me additionally what am I looking at for this drug X, Y, Z, what does a hundred of them cost a pharmacy? I didn't look at Red Book or Blue Book or First Data; I called the people that sell it. . . .

(3/12/2008 Sullivan Dep. at 106:18-107:22, Ex. 1.)

> Q. But you used a MAC program to reimburse generic drugs; is that right?
> A. Yeah. Now I thought you were talking about brand name in your original question. I keep the two totally separate. I have never reimbursed anybody for generic based on AWP.
> Q. So would it be fair to say that you believed you had another choice to set reimbursement rates for generic drugs?
> A. Oh, yes.
> Q. Apart from the compendia.
> A. Yes. Yes. I'm sorry.

(*Id*. at 115:20-116:10.)

United States' Response: Undisputed.

Defendants' Statement [79](b): Ohio's Robert Reid testified:

> Q. So the prices that you used to set the MAC amount, those were based on actual prices that you got from pharmacies; correct?
> A. Right.
> Q. They are not based on—
> A. Well, partly, yeah.
> Q. What else were they based on?

A. Well, we would take the First DataBank price into consideration, although rarely use it on the grid, unless it was reasonable, comparable.
Q. So if the First DataBank price was not comparable to the other prices, you wouldn't use it?
A. No. I would consider it to be an outlier.
Q. If it was an outlier, it wouldn't even go into the 65th percentile calculation?
MS. GEOPPINGER: Object to the form of the question.
Q. You can answer.
A. Yes.
Q. And you did all this by yourself?
A. I did it all by myself up until 2001.

(12/15/2008 Reid Dep. at 160:19-161:20, Ex. 2.)

United States' Response: The United States objects to defendants' Paragraph 79(b) because, as the United States has told the defendants, the United States does not seek damages with regard to Ohio.

Defendants' Statement [79](c): Maryland's Joseph Fine testified:

Q. So you got pricing information from either wholesalers or a pharmacist who cooperated with the department in giving—
A. But it was from wholesalers. It was always wholesale prices. It was the wholesaler file. But since they wouldn't let us use it directly we had to go through them to get the files.
Q. When you say wholesale file—
A. Meaning the price list. The drug price list.
Q. We're not talking about the compendia here?
A. No. Maryland did not use compendia, meaning we did not use First Databank and/or Medi-Span to set our IDC. We were determined to set our state MAC or IDC based on what local—what our pharmacists could get the drug for if they were working and buying the product from a wholesaler that was selling in Maryland.
Q. And this process of going to get wholesale price lists from either a wholesaler or a pharmacist, some of that was just part of your job, right?
A. Correct.

Q. Something you felt you needed to do to get fair pricing for drugs?
MS. YAVELBERG: Objection, form.
A. Well, the feel—it's not my feeling. It's what Maryland decided to do to get fair pricing to their pharmacists who fill prescriptions for Maryland medical assistance recipients.
Q. And you received cooperation from the pharmacy providers in this effort?
MS. YAVELBERG: Objection, form.
A. Yes. Yes. The pharmacy providers worked with us.

(12/9/2008 Fine Dep. at 203:8-204:19, Ex. 91.)

United States Response: Undisputed as to the source of pricing information used to set MACs.

Defendants' Statement [79](d): Nebraska's Gary Cheloha testified regarding how Nebraska established MACs:

Q. Once you determined that there's a particular drug that you'd like to set a maximum allowable cost for, how do you go about setting that actual price?
A. Ask for a recommendation from Pace Alliance. We'll also call pharmacies to determine the range of costs or range of recommended—recommendations for SMAC pricing.
Q. Okay. So if you find out from Mr. Woods at Pace that, for a particular prescription drug, that he can purchase it for, say, 50 cents for that particular dosage, I mean, do you use that figure? Or is there a calculation involved in taking that number and turning it into a MAC?
A. Into an actual SMAC price?
Q. Uh-huh.
A. There is no set formula, and he doesn't provide us—I think he has—I believe he has confidentiality agreements for the actual price that the Alliance members can purchase the drug for. So—and we rely mostly on the Pace recommendations.
Q. So he'll give you kind of a range, and you'll—
A. He'll generally quote a specific price. He'll say 8 cents, 10 cents. I recommend this for the SMAC price on it.
Q. And do you know—you said that there's some confidentiality provisions as far as what they're actually paying. Do you know if he bills in some percentage or a few cents here or

there to make sure that other people can get that or to account for profit or anything like that?

A. All I would know for sure is that it's more than the contract price, but I don't know whether he uses a specific formula or how he specifically determines that. He—from time to time, on a very limited basis, he and I have discussed—how will I say it—the price that the pharmacies pay. And then I would—when I was doing it, I made a determination of where to set the MAC price, at something above that.

Q. And did you have a formula, or you were just—it was a case-by-case basis for—

A. Generally, a case—it was a case-by- case basis. I did not have a set formula.

Q. And I'm assuming that the—you said that Pace is a purchasing organization that has pharmacies in Nebraska, and those pharmacies are participants in the Medicaid program?

A. Yes.

(12/2/2008 Cheloha Dep. at 128:13-132:17, Ex. 28.)

***United States' Response*:** Undisputed as to the source of pricing information used to set MACs.

Defendants' Statement [79](e): Michigan's Sandra Kramer testified that a pharmacist consultant provided utilization data on generic drugs to help establish Michigan Medicaid's MAC prices:

Q. Were you responsible from 1990 through the time you left for setting state MACs?

A. Yes.

Q. Okay. How were those set during that time period?

A. During that time period, the best that I can recall is that we had a pharmacist consultant with the department. I don't remember how frequently he came in, but periodically he would come in and I would provide him with utilization data on the generic drugs and he would do research of maybe what other states or another insurer would have priced MAC at, and then also he would have availability of wholesaler information and would establish target MACs, and then I would take those target MACs and publish them in drafts for comment with the pharmacist and other people that were interested in pharmacy issues.

* * *

Q. And did this—you stated this pharmacist consultant had access to wholesale prices?
A. He was a practicing pharmacist.
Q. So he knew what his actual acquisition costs would be for particular drugs?
A. I assume so. . . .

(3/25/2008 Kramer Dep. at 144:10-145:21, Ex. 4.)

United States' Response: Undisputed as to the source of pricing information used to set MACs.

Defendants' Statement [79](f): Georgia's MAC rates are set by its PBM pursuant to the PBM's proprietary formula. (12/15/2008 Dubberly Dep. at 207:3-208:8, Ex. 24.)

United States' Response: Disputed. Defendants have quoted this testimony out of context. Mr. Dubberly also testified that the PBM formula referenced in the above quote did not commence until after July of 2000, and that the MACs were set by reference to AWPs. (12/15/08 Dubberly Dep at 36:1-5, 75:11-15, Henderson Reply Ex. 12.) Responding further, Georgia had a MAC program to "try to comply with the federal regulations of reimbursing closer to the actual acquisition cost," to "save money," (*id.,* at 69:01-09) and so that reimbursement would "be more reflective of their actual acquisition cost in the market." (*Id*., at 67:16-19)

Defendants' Statement [79](g); New Hampshire state received MAC prices from its pharmacy benefit manager, First Health Services, which used a proprietary formula to calculate MAC prices. (10/29/2008 Clifford Dep. at 66:11-67:10, Ex. 106.)

United States' Response: Undisputed as to the source of pricing information used to set MACs.

Defendants' Statement [79](h): Since at least July 2002, Illinois Medicaid has considered pharmacy acquisition cost information as part of its MAC program. (Ex. 150

(Roxane IL Ex. 10). "DHFS would review pharmacy acquisition cost information to verify that the products were available at or below the MAC price." (*Id*., at 5)

United States' Response: Undisputed as to the source of pricing information used to set MACs; however, the exhibit cited does not contain testimony by state officials, and does not support the fact or contain the referenced quote.

Defendants' Statement [79](I): Washington Medicaid determined its state MACs based on surveys of the three largest wholesalers' prices in Washington and negotiations with the Washington State Pharmacy Association. (11/24/2008 Wimpee Dep. at 105:9-107:13, Ex. 151.) An internal Washington Medicaid document stated that MAC were set after discussions with pharmacists to assure that MAC prices were "workable, fair and consistent." (Ex. 152 (JD WA 1570-87).) In 1997, Washington implemented an automatic maximum allowable cost ("AMAC") methodology to compute state MACs not otherwise on Washington's MAC list. Under this methodology, "AMAC reimbursement for all products within a generic code number sequence shall be at the estimated acquisition cost (EAC) of the third lowest priced drug in that sequence, or the EAC of the lowest priced drug under a federal rebate agreement in that sequence, whichever is lower." (Ex. 153) (HHC018-0045-50).)

United States' Response: Undisputed as to the source of pricing information used to set MACs.

Defendants' Statement [79](j): According to Jude Walsh, former Division Director for Health Care Management for Maine Medicaid, Maine requests invoices from pharmacies and reviews the invoice prices in the process of setting MACs.

Q. Do you know how the state went – goes about setting a MAC?
A. Yes.
Q. And how does it do that?
A. We look at the number of generic manufacturers. It is typically for generics, the generic manufacturers that are producing medications. We look at invoices to see the spread between the reimbursement and the acquisition, and we – we implement caps on the – setting caps for the maximum amount that we'll reimburse for those drugs.

(3/26/2008 Walsh Dep. at 94:5-16, Ex. 154.)

Q. And do you – what do you mean by acquisition cost?
A. The amount of – the amount of money it costs the pharmacy to acquire a medication.
Q. And how would Maine determine that?
A. We – we ask for invoices.
Q. You ask for invoices in the process of setting a MAC?
A. We do because we have pharmacies that complain that our MAC's are too low and we say send us an invoice so we can see.
Q. How often does that occur?
A. We set our MAC's monthly. We are always updating our MAC list.
Q. Do the pharmacists call pretty regularly then?
A. If they have a concern.

(*Id*. at 97:20-98:14.)

United States' Response: Undisputed as to the source of pricing information used to set MACs.

Defendants' Statement [79](k): Arkansas Medicaid established its MAC calculation based on invoice prices that pharmacies share with Arkansas Medicaid in order to approximate the actual acquisition cost. (12/10/2008 Bridges Dep. at 65:3-11, 244:14-246:1, Ex. 109.)

United States' Response*:* Disputed to the extent defendants are asserting that Arkansas Medicaid has always based its MAC calculation on invoice prices that pharmacies share with Arkansas Medicaid. The Arkansas Medicaid witness testified as to the MAC program's current operation, which involves an employee of the Medicaid contractor contacting pharmacies telephonically and asking them for their invoice prices for certain drugs. (12/10/08 Bridges Dep. at 301:7-17, 244:3-22–252:1-5, Henderson Reply Ex. 31.)

Defendants' Statement [79](l): North Dakota's Brendan Joyce testified:

Q. Okay. And do you know how Chad Jones sets MAC prices for the department?

A. He evaluates actual acquisition costs from surveys that – wholesalers that he's – has contacts with. So he contacts wholesalers to get the actual acquisition costs of products. Compares his MAC pricing to other MAC price lists that are out there and available. And he tries to set the MACs at a rate that will encourage generic utilization, yet – and also give appropriate adequate reimbursement based on the formula, the rest of the reimbursement formula with the state.
Q. During the time North Dakota Medicaid set its own MAC prices it did not rely on AWP to set those prices, correct?
A. We still set some of our own MAC prices. So –
Q. Okay.
A. We do – we have not – never have and never will care what the AWP is. In the setting of those MACs.

(12/12/08 Joyce Dep. at 128:21-129:20, Ex. 19.)

United States' Response: Undisputed, except that defendants have quoted this testimony out of context. Mr. Joyce testified that the MAC program was set in response to the inconsistencies of the manufacturers' reported pricing.

Q. At the time when you recommended to the North Dakota Medicaid department that it institute a MAC program, was it your observation that AWPs for generic drugs were often random by which I mean not a set or knowable percentage differential from actual acquisition prices?
MR. MALONEY: Objection to form.
A. The difficulty we had, the other option besides MAC is to set AWP minus, you know, the reference price minus percent. And the reports would show minus 40 percent for the average, but that's just the average. Therefore, we couldn't use it specifically because of exactly what you say, it was random from product to product, manufacturer to manufacturer. Since it was so random we couldn't use the AWP in the calculation of the price. We had to use MAC.

(12/12/08 Joyce Dep. at 270:13-271:7, Henderson Reply Ex. 9.)

80. State officials provided testimony regarding the factors that influenced how their states established MAC pricing levels.

United States' Response: The United States does not dispute that various state officials provided testimony that a number of factors influenced how their state established MAC pricing levels. However, the United States disputes that the specifics of any State's MAC program are material to any issue presented in the summary judgment motions. The United States' theory of recovery and damages model are not based upon defendants' false price statements causing inflated MACs; rather, the United States asserts that defendants' false price representations caused EAC to be inflated, and thereby caused damages whenever the original reimbursement amount – whether based on EAC, MAC, FUL, or U&C – was higher than it would have been but for the inflated EAC. All or nearly all States would have based reimbursement on EAC had it resulted in a lower amount. (Henderson Common Ex. 24 (Knerr Decl.) ¶ 18, 19, 24.)

Defendants' Statement [80](a): Florida Medicaid's Jerry Wells testified:

> Q. When you established those MACs, were you trying to set the MAC at exactly the acquisition cost of providers or at some point above or below the acquisition cost for providers?
> A. We would not have tried to set acquisition or the reimbursement level below acquisition cost. We would try to set the reimbursement level at a point where 95 percent of the providers could purchase the drug at or below that price.

(12/15/2008 J. Wells Dep. at 229:22-230:10, Ex. 12.)

United States' Response: Undisputed, except that defendants have quoted this testimony out of context. Mr. Wells testified that,

- it was always the goal of Florida Medicaid "to be able to set reimbursement levels according to the guidelines we were given by the state legislature and by the feds, and to that end, it was our desire to know what true cost was." (12/15/08 Wells Dep. at 254:12-254:16, Henderson Reply Ex. 6); and

- Florida Medicaid was "trying to approximate the price that is generally and currently available in the marketplace" and that Florida Medicaid's "estimated acquisition cost is what most pharmacies are able to buy the drug." (5/26/05 Wells Dep. at 709:8-709:11, Henderson Reply Ex. 7)

Defendants' Statement [80](b): Tennessee's H. Leo Sullivan testified:

Q. And do you know in Tennessee, either before TennCare or after TennCare was paying a compounding fee for IV? Do you know if that was something that was being paid?
A. Ah, no. But there's, there's ways to pay it without, without having a separate—you know, I noticed on here that one form is for payment, one form is for reimbursement of supplies, one form is for—you know, they're, they're making a variety to submit multiple forms. And I wouldn't—I can't tell you a specific product or specific time period, but one of my strategies was in issues like this, where compounding was involved, I didn't want to go down the road, at least in the early Nineties, of getting into paying for compounded prescriptions, because that can—that could range from a sterile product all the way down to an ointment, okay? And, and our claims reimbursement system hadn't evolved to the current NCPDP sophistication of today. So it was very hard to put in a, a set compounding fee for what, what products? One may take a minute to make, one may take an hour and a half. So getting back to, to the MAC issue, some, sometimes for certain products in this arena, you would take that into account for the MAC. For example, I might say, I'm not paying for the tape that you use to hold the IV needle into place. I'm not paying for the IV needle or the tube set. I'm not going to—I don't want bills for that. I know you've got to do it to administer this drug. So we're going to add on the cost of this drug X, because I know this, this and this always goes with it, and I know there is a fixed cost for that, but I don't want five bills. I want 10 different places. Bill me for the drug. And I'll make sure that the—whatever the MAC is incorporates all your other costs. And you have to talk with providers and know what that is. I mean, you know.
Q. So, in short, you would use the payment for the drug itself to cross-subsidize other things that might need to be paid to fairly—
A. And that would include compounding.

Q. And it may include nursing services that were not included, things of that nature?
A. (Nodding yes.)

(3/12/2008 Sullivan Dep. at 152:16-154:22, Ex. 1.) According to Sullivan, Tennessee encouraged the use of generic drugs over brand drugs by including a higher profit margin into reimbursements for generic drugs, which was also a way to save the state money. (Id. at 60:12-61:14; 62:13-63:10.)

***United States' Response*:** The United States does not dispute that defendants have correctly, but selectively, quoted from Mr. Sullivan's testimony.

Defendants' Statement [80](c): Washington's Ayuni Hautea-Wimpee, the Pharmacy Unit Manager for Washington Medicaid, testified:

Q. And when setting AMAC, you would look at pricing available to wholesalers?
A. From wholesalers, yes.
Q. Excuse me, from wholesalers?
A. Um hum.
Q. In Washington State?
A. Yes.
Q. Okay. And you would look at an array of those prices and determine at what price pharmacists could actually obtain the product for?
A. Correct.
Q. And you mentioned that one concern was access; is that correct?
A. Yes.

(11/24/2008 Wimpee Dep. at 108:4-18, Ex. 151.)

***United States' Response*:** Defendants have correctly, but selectively, quoted from Ms. Hautea-Wimpee testimony.

Defendants' Statement [80](d): Minnesota's Cody Wiberg testified:

Q. Mr. Wiberg, I'd like to -- or Doctor Wiberg. I apologize for that. I've been calling you "Mr." all day. I would like to take you back to the Zantac example you gave earlier.
A. Yes.

Q. I think you said the AWP was 90 cents.
A. Around there, yeah.
Q. The MAC was about 25 cents, and the AAC was about 6 cents, right?
A. Well, the – the actual acquisition costs for the store I worked as was – was – was around 6 cents, as I recall.
Q. So 25 cents is what the State Medicaid Program chose to pay for that 6 cent pill, right?
A. That's correct.
Q. Isn't that about a 400 percent spread, between 6 and 25?
A. Well, again, you can't – people don't spend percentages. They spend dollars. And what the goal was – and I don't have a calculator handy, but if you do the math, typically we're talking about 60 tablets. In a typical prescription. So, you know, the actual math is – is they're not getting huge amounts of actual dollars. And at some point, I think we reduced the MAC. Part of – well, let me just say that when I came on board at the Minnesota Department of Human Services, there was one pharmacist working. We used the pharmacy program manager, he was working there by himself. He had three rebate analysts. There had been more pharmacists working for the Department earlier, but they worked in different divisions. In fact, there wasn't a pharmacy program a year-and-a-half before I started. There was no coherent Pharmacy Management Policy. And as a result of that, we made – after I took over, we ended up making massive changes. It went from, in my opinion, being a program that was not very effectively managed, to being one that is very aggressively managed now. So – and the other issue that we had – I mentioned earlier was that my predecessor, because he introduced this language that ended up getting amended, took away our authority to do a lot of things with – with MACs. So part of what we were trying to do, although we had to accelerate when we got to 2002 and 2003, we had no choice. Part of it was to not shock the system, which had essentially been unmanaged. So we're trying to introduce these changes in a – I wouldn't say gradual, but we're trying to not hit people with so many things at once that we cause disruptions to service, or that, quite frankly, because it's a political environment, that it backfires on us, and we do have people going to the legislators, saying, basically, these people over at DHS are out of control, and have our authority to make the changes we thought were necessary taken away from us. So we didn't always do things initially as aggressively as we might have in the time frame we're talking about here, 2000, 2001. 2002, 2003, when we're starting facing budget deficits, even before then, we had started ramping up

and doing preferred – you know, our own internal preferred drug list for some categories. But we got very, very aggressive at that point. And so these days, as I mentioned earlier, we increased the use of generics because of the MAC program from about 50 percent when I started to 60 percent. It's now up to 69 percent. So -- you know -- anyway.

Q. But in these generics MACs that you're setting are shooting for a dollar amount spread –

A. Right.

Q. -- not necessarily for a correct percentage spread, right?

A. That's correct.

Q. And the correct percentage could be a thousand, could be 2,000, could be 1 percent, depending upon the starting cost of the product, right?

A. Yes, we are searching for a dollar spread, not a percent spread.

(3/14/2008 Wiberg Dep. at 356:19-360:13, Ex. 68.)

United States' Response:. The United States does not dispute that defendants accurately quoted excerpts of Mr. Wiberg's testimony. Further answering, *see infra* United States' Response to Paragraph 41(b).

Defendants' Statement [80](e): South Dakota's Larry Iverson testified:

Q. If you look at the second bullet point at the third sentence, it states, "The MAC price is then applied across all package sizes available, but is structured to insure that the profit to the pharmacist to dispense the generic product is higher than that associated with dispensing the brand product. This strategy provides pharmacists with an incentive to dispense generic products as well as to make recommendations to prescribers that they substitute brand products with generic therapy alternatives." As we established earlier, providing the provider with a profit was an important concern to South Dakota Medicaid, correct?

A. Yes.

(12/15/2008 Iversen Dep. 99:15-100:8, Ex. 86; Ex. 113 (Dey Ex. 911).)

United States' Response: The United States does not dispute that defendants accurately, but selectively, quoted excerpts of Mr. Iversen's testimony. The quotation, however, is out of

context. First, the quotation included in defense counsel's question came from a letter of a company called SXC Health Solutions, Inc. ("SXC"). The letter was in response to South Dakota's Request for Proposals from entities interested in providing SMAC prescription drug pricing data. (*See* 12/15/08 Iversen Dep., at 85:16- 86, and Attachment 2 of Dep. Ex. Dey 911, Henderson Reply Ex. 38)

Although SXC was retained as a contractor by South Dakota, Paragraph 1 of the contract between SXC and the State of South Dakota specifically states that, "...while performing services hereunder, Consultant is an independent contractor and not an officer, agent, or employee of the State of South Dakota." (*See* 12/15/08 Iversen Dep. at 85:16-86, and page 1 of the Contract in Dep. Ex. Dey 911 (Group Exhibit includes the Contract between SXC and South Dakota, Attachment 1 which is the Request for Proposal, and Attachment 2 which is SXC's Response to the Request for Proposal), Henderson Reply Ex. 38.)

In addition, the Request for Proposal issued by the State of South Dakota shows that South Dakota was implementing SMAC pricing not for the purpose of allowing the payment of a margin on ingredient cost, but to set the maximum allowable price based on the cost at which the drug is available to South Dakota pharmacy providers. South Dakota's Request for Proposal states:

> The South Dakota Medical Assistance Program implemented State Maximum Allowable Cost (SMAC) pricing in 2002. Current SMAC pricing is implemented for drugs that are widely and consistently available to South Dakota pharmacies at a price that is less than the average wholesale price. The maximum allowable price for each drug is based on the cost at which the drug is available to South Dakota pharmacy providers.

(*See* 12/15/08 Iversen Dep. at 85:16-86, and page 1 of Attachment 1 of Dep. Ex. Dey 911, Henderson Reply Ex. 38.)

Defendants' Statement [80](f): Ann Rugg, former Deputy Director of Vermont Medicaid and Vermont's 30(b)(6) witness, testified that Vermont Medicaid set MAC prices that would ensure profit to providers:

> Q. Well, your explanation that you just stated on the record, would you say that that is the rationale for Vermont also implementing the MAC program?
> A. The reason Vermont wanted to implement a MAC program was to manage the price of generics at a level using this particular model at a level where a store could still make a profit, yet that the program itself would not be paying an exorbitant rate. …
> Q. And you also testified that some sort of profit or reasonable profit was – well, let me rephrase that question. Was it Vermont's goal also to ensure some sort of reasonable profit for pharmacy providers?
> A. Yes.

(12/15/2008 Rugg Dep. at 210-212, Ex. 156.)

United States' Response: Undisputed, except that defendants' quotation is selective and incomplete. Ms. Rugg testified that the purpose of Vermont's MAC program was to ensure that Vermont Medicaid reimbursed pharmacists at levels approximating drugs' lowest available purchase price.

> So the MAC is more in recognition of what the regional access to the products are. So the idea is if you have multiple AB-rated generics is to reimburse at a level where pharmacies can purchase but not at the highest cost, in fact at the lower cost options, if you will, so that we're not artificially -- we as a program are not artificially paying or paying a greater amount based on what they stocked as opposed to what was available.

(12/15/2008 Rugg Dep., at 117:8 -117:9, Henderson Reply Ex. 66.) Ms. Rugg also testified that Vermont regarded its dispensing fee as adequate to ensure provider participation levels. (*Id.*, at 255:13 - 255:15, 261:12 - 262:21.)

Defendants' Statement [80](g): Maryland produced a document titled "Proposed Sliding Scale Reimbursement Formula For Generic Drugs." (Ex. 157 (Abbott MD Ex. 17).) This document depicts a chart showing a range of generic drug costs (per tablet and Max. Cost per 30 tablets) and the corresponding "percent mark-up" and "range of profit per 30 tablets." (*Id*.) According to this table, the percent mark-up increases for inexpensive drugs while the range of profit per 30 tablets remains relatively constant. (*Id*.)

United States' Response: Disputed. This citation refers to an exhibit that contains no identifying information as to who prepared it, when it was prepared, or why it was prepared. Therefore it is hearsay, irrelevant, and inadmissible. The exhibit does not purport to represent how Maryland established its MAC pricing, nor does it in fact represent how Maryland calculated its MAC pricing. Mr. Fine, the Maryland witness, did not recognize or know the origin of the document.

81. Ohio's Robert Reid testified regarding whether states had to rely upon prices reported in the compendia to adjudicate claims for generic drugs:

Q. Now, here Ohio did not pay prices that were 1,000 percent higher than Abbott's actual prices, did it?
A. Ohio did not.
Q. So at least in Ohio, Abbott's alleged misconduct did not ensure its customers of receiving inflated reimbursement; right?
MS. GEOPPINGER: Object to the form. You can answer.
A. I would say yes.
Q. How's that?
A. How is that?
Q. You would say that it did not ensure that Abbott's customers were –
A. Well, we didn't pay attention to AWP and WAC, so, therefore, we don't – we didn't pay pharmacies more than what we should have based on our methodology.
Q. So at least in Ohio, these prices did not ensure that Abbott's customers would receive inflated reimbursement in profits; correct?
MS. GEOPPINGER: Object to the form of the question. You can answer.
A. To the best of my knowledge, that's true.

Q. It's because the State of Ohio controls what the State of Ohio will pay on claims for Abbott's drugs; correct?
A. Correct.
MS. GEOPPINGER: Object to the form of the question.
A. As with other manufacturers as well.
Q. Go to page 2, Paragraph 3.
A. 3, okay.
Q. The second sentence, it's the fourth line down of that paragraph, it starts on the right with the word "In."
A. "In," I got it.
Q. States, "In furtherance of this scheme, Abbott reported false, fraudulent and inflated drug prices for certain drugs listed in the Paragraph 31 – Paragraphs 31 and 35 below, to several price reporting compendia that the Medicare and Medicaid programs were relied upon to set reimbursement rates for Abbott's customers." See that?
A. Somebody said that. I didn't say it.
Q. Ohio did not rely upon the compendia prices to set reimbursement for Abbott's customers –
A. That's correct.
Q. And no state had to rely upon those prices if they chose not to; correct?
MS. GEOPPINGER: Object to the form of the question.
MR. HENDERSON: Objection.
MS. GEOPPINGER: You can answer.
A. I don't think it was mandatory for any state to rely on compendia prices.
Q. Any state could have done what you did –
A. Or–
Q. – and set a MAC price?
MS. GEOPPINGER: Object to the form of the question. Go ahead. Is that a question?
MR. TORBORG: Yes.
MS. GEOPPINGER: Is the question could they have done that?
MR. TORBORG: Yes.
THE WITNESS: Oh, they could have, yes.
MS. GEOPPINGER: Same objection.
BY MR. TORBORG:
Q: And you managed to do this MAC program and avoid this whole problem all by yourself in Ohio; right?
A. I'm –
MS. GEOPPINGER: Object to the form of the question.

A. As far as I know, I'm the only one that did it.

(12/15/2008 Reid Dep. at 221:21-225:16, Ex. 2.)

United States' Response: The United States objects on the ground that the exhibit submitted by the defendants does not set forth the testimony quoted. In addition, the United States does not seek damages with respect to Ohio and therefore the testimony is irrelevant. In addition, the purported testimony about what other States could have done is inadmissible because there is no foundation that would qualify the witness to testify about what other States could or could not have done.

82. Tennessee's H. Leo Sullivan testified regarding the importance of MAC pricing:

> A. The question, though, that, that boggles my mind, and it did at this time when I interacted with my peers, when they're wringing their hands over issues like this, I'm just --you know, I'm just curious why you don't get out there, find out what the drugs cost, and set the price yourself. You can always MAC things. You can MAC a brand name drug if you want to. But go ahead.

(3/12/2008 Sullivan Dep. at 240:4-12, Ex. 1.)

United States' Response: The United States does not dispute that defendants accurately, but selectively, quoted from Mr. Sullivan's testimony. The United States disputes the materiality of the above statement. Further responding, numerous state Medicaid officials testified they required accurate, current and comprehensive pricing information to process millions of claims for reimbursement on many thousands of different products, and that it was possible for states to process this volume of claims without relying on published pricing. *See generally* United States' Common Statement of Facts (Dkt. No. 6316, 312), ¶¶ 23-24.

83. Maine's Judge Walsh testified regarding how Maine reimbursed for physician administered drugs based on acquisition cost:

> A. That's incorrect. Physicians – J codes are administered by the provider in the office setting. So typically they are an injection or an infusion and they are drugs that the physician bills the acquisition cost and the visit.
> Q. So it is an acquisition cost and you are looking at the invoice then?
> A. We certainly can call in the invoice, the invoice can be produced if we request it.
> Q. And how -- do you know how the physicians determine acquisition cost?
> MS. ST. PETER-GRIFFITH: Object to the form.
> A. Physicians don't determine acquisition costs, physicians have invoices that show what they acquire the drugs at, that's – that's acquisition.

(3/26/2008 Walsh Dep. 110:6-111:1, Ex. 154.)

United States' Response: The United States does not dispute that defendants accurately, but selectively, quoted excerpts of Ms. Walsh's testimony. The quoted testimony is not material to this litigation, as the United States is not seeking damages for state Medicaid J-code reimbursements to physicians.

84. New Jersey's Ed Vaccaro testified regarding how New Jersey reimbursed for physician administered drugs based on acquisition cost:

> Q. Okay. And is there a physician claim form that requires the physician to submit its actual acquisition costs or its acquisition costs as it's defined here?
> A: The acquisition cost would be reflected as their charge on that claim form.
> Q. How is charge defined for a physician?
> A. In the case of an injectable?
> Q. Yes. In the -- well, in the case of an injectable and inhalation drug.
> A. It would be his acquisition cost.
> Q. How would it -- how would a physician compute its acquisition cost?

A: Be an invoice.
Q. This is an invoice that the – that reflects the payment that the physician --
A. Purchased.
Q. -- made for the purchase of the pharmaceutical?
A. The purchase of the injectable, correct.
Q. Okay. Now, if you go -- and your understanding is this is not the same thing as the average wholesale price; correct?
A. Correct.
Q. Okay. Which is consistent with your application of regulations in general that you apply the literal meanings of the regulations; correct?
A: Correct.

(12/3/2008 Vaccaro Dep. 519: 7-520:20, Ex. 80.)

Q. The actual – the physicians submitted in their claims the actual acquisition costs for injectables –
A. That is correct.
Q. -- is that correct?
A. That is correct.
Q. And I was unclear in your earlier testimony what they were submitting. Was it the actual – was it the actual cost that the physicians paid for those drugs?
A. Yes.
Q. Did New Jersey give any guidance to the physicians as to how they should calculate their actual acquisition costs?
A. It was – it was – now, I'd have to reference the physician's manual to be sure, okay, but it would be their costs, their invoice costs.
Q. Did you tell them whether or to what extent discounts or rebates should be included if they were not reflected in the invoice?
A. No, I -- again, it was expected it would be their actual cost, whatever that was. The bottom line. If there were discounts or rebates involved, we expected to receive a number that reflected their purchase cost.

(*Id*. at 668:10-669:13.)

United States Response: The United States does not dispute that defendants have accurately, but selectively, cited excerpts from Mr. Vacarro's testimony (although the quoted

excerpt fails to include objections made by the United States.) Mr. Vaccaro further testified that the rubric for reimbursement to physicians involved not only acquisition costs, but the use of procedure codes derived from median AWPs. (12/3/08 Vaccaro Dep. at 670:3-20, Ex.40.)

85. Delaware Medicaid reimburses pharmacies and other providers that qualify for "special purchasing" such as 340b pricing and Robinson Patman Act purchasers based on actual acquisition costs, which those providers must submit as part of their claim for payment. (12/9/2008 Denemark Dep. at 108:4-112:2, Ex. 22.)

United States' Response: The United States does not dispute that the witness testified as cited. The defendants' quotation, however, is selective, incomplete, and misleading, and the United States therefore disputes the implied import of Paragraph 85. In fact, the witness testified that Delaware had moved away from reimbursement based on actual acquisition cost because it was impossible for the state to audit, and officials suspected pharmacies were not submitting accurate prices. Any suggestion that the witness's testimony supports the idea that Delaware could have reimbursed all claims based on actual acquisition costs is false. The witness testified:

> Q. Yesterday you testified that the state – and I think again today, that the state could have continued to use actual acquisition costs as the estimated acquisition costs or EAC in its reimbursement formula. Did I remember that correctly?
> A. That's correct.
> Q. And yesterday you said you would not have recommended that; is that right?
> A. That's correct.
> Q. Why not?
> A. Because, to the best of my knowledge, the pharmacies were not submitting the actual acquisition cost plus the dispensing fee. And if they were, and if they were part of a chain, then the actual acquisition costs that they were charged based on their distribution center because of the chain was not a reasonable rate that the Division should be reimbursing at. It was, in my opinion, and what I would have recommended to the Division, an inflated rate.
> Q. Why not audit the pharmacy invoices as you did in 2002?

> A. Well, several reasons why not to audit: Number one, it is a very time-consuming and expensive process. In some situations, as I testified, Rite-Aid wouldn't even release all of their information. And I am not confident that even with trained auditors we would have been able to look at all of the different elements that might have related to an overall total cost of a full set of prescriptions that were ordered.

(12/10/08 Denemark Dep. at 474:17-476:4, Ex. 11.)

86. DOJ's expert admits he simply "assumed" for all claims that, if lower compendia prices were reported, payments would have been based on those prices. (Duggan 5/19/09 Dep. at 345:14-16 (Medicaid), Duggan 2/27/09 Dep. at 420:14-16 (Medicare).)

United States' Response: Disputed. Defendants have quoted Dr. Duggan out of context. Many of the questions before and after the cited testimony were directed to the knowledge of Medicaid officials, and the questions called for speculative answers about whether Medicaid officials might have changed reimbursement methodologies in certain circumstances. *See* Duggan 5/19/09 Dep. at 343:7 to 345:6, Henderson Reply Ex. 101. The questions did not ask about a situation where the defendants stopped reporting inflated prices, and the resulting more accurate AWPs would have been used in the existing state methodologies. Dr. Duggan also testified that he saw that when Abbott slashed its prices in 2001, the claims were in fact processed using those substantially lower prices and there was a resulting drop in expenditures by the Medicaid programs as a result. See Duggan 5/19/09 Dep. at 344:9 to 347:17. Dr. Duggan also took into account situations where a state did not apply the "lower of" methodology, as in the case case of New York, which, for drugs subject to a FUL, pays based on the FUL even if the EAC is lower.

L. FULs

87. From 1987 to 2006, the FUL regulation permitted the Government to establish a "federal upper limit" for qualifying generic drugs at 150% of the published price for the least costly therapeutically equivalent product. (Dey SOF at ¶¶ 239, 241.)

United States' Response: Undisputed. Further responding, CMS may only set FULs for multiple source drugs that meet certain statutory criteria and regulatory requirements, including that there be at least three therapeutic and pharmaceutical equivalents, as reflected in the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as the "Orange Book"). 42 U.S.C. § 1396r-8(e)(4) In addition, there must be at least three suppliers for a FUL drug, as reflected in all listings contained in current editions (or updates) of published compendia of cost information for drugs available for sale nationally." 42 C.F.R. § 447.332(a)(1)(ii) .

> 88. With the exception of six NDCs, 0007-46138-02, 0074-6138-03, 0074-6138-22, 0074-7138-09, 0074-7924-09, 00074-7972-05 each of the 44 Complaint NDCs in the Abbott case met the criteria for the establishment of a FUL during the relevant time period. (Ex. 158 at 32 n 51) (Expert Report of Steven J. Young) ("The majority of the NDCs in this matter met the requirements to have a FUL calculated, but the CMS did not do so.").)

United States' Response: The United States does not dispute that most of Abbott drugs at issue in this litigation met the regulatory criteria for establishing a FUL. The United States further admits that CMS did not set FULS for each and every drug that met the regulatory criteria. CMS policy was generally to attempt to set FULs for eligible drugs that were the most commonly used and dispensed by pharmacies. (Fauci Exhibit 146 (3/19/2008 Sue Gaston Dep.), at 322:20 - 323:6; Fauci Exhibit 147 (1/24/2008 Sue Gaston Dep.), at. 250:7 - 250:22.) As Ms. Gaston explained, CMS generally did not set FULs for injectable products:

> Q. And we'll talk about that in a bit. Why don't we talk about it now. Why are not injectable products included on the FUL?
> MR. WINGET-HERNANDEZ: Objection, form.
> A When I started to work on the FULs injectable products were not included. And it's my understanding that the purpose of the FUL program is to set reimbursement rates on drugs that are generally used by the Medicaid population in an

> outpatient-type, like a pharmacy-type setting, most commonly used products. And it's my understanding that injectables and other products many times are provided in a physician's office and other type of settings where they might not be claimed separately. They might be included in a payment, like a physician payment. Also, injectables, many times when they're billed on the claim form they're not – they're billed with codes rather than NDC numbers, which means that the states may not be paying for them through their pharmacy benefit but through another means, such as a physician's visit or a hospital or something like that. So many times what we're trying to do with the FULs is use most commonly used drugs and covered outpatient drug type, so like tablets and capsules.

(1/24/08 Sue Gaston Dep. 245:13-22; 246:1-16.)

89. Although most of the drugs in this case met the regulation's requirements, CMS sometimes did not establish a FUL for a particular drug, or removed a FUL for a particular drug, because of concerns about the availability of the drug. (Dey SOF at ¶¶ 244-247.)

United States' Response: The United States further admits that CMS did not set FULS for each and every drug that met the regulatory criteria. The paragraph is otherwise disputed, as it is not supported by the cited authority. Further responding, CMS policy was generally to attempt to set FULs for eligible drugs that were the most commonly used and dispensed by pharmacies. (Fauci Exhibit 146 (3/19/2008 Sue Gaston Dep.), at 322:20 - 323:6; Fauci Exhibit 147 (1/24/2008 Sue Gaston Dep.), at. 250:7 - 250:22.)

90. There was no formal guidance for how or when to not set, or to remove, a FUL for a qualifying drug; this review was left to CMS's discretion. (Dey SOF at ¶ 244.) CMS officials were informally taught by other CMS officials how to exercise their discretion to set FULs manually so as to meet the dual objectives of cost savings and access. (1/24/08 Gaston Dep at 225:16 -226:7, Ex. 34; 5/20/08 Sexton Dep. at 73:14-74:22, Ex. 159.)

United States' Response: Disputed insofar as the cited authority does not support this paragraph. The United States in this case is not proceeding on a "FUL theory of liability," and therefore this paragraph has no bearing on the instant case.

The United States' further states that CMS utilized a program known as the Federal Upper Limit System ("FUL System") in setting FULs, and that the FUL System downloaded information from the FDA's Orange Book as well as information from pricing compendia to create listings of reported prices for drugs statutorily eligible for a FUL. *See generally* United States' Response to Dey SOF, ¶ 244. CMS employees then reviewed the price listings generated by the FUL System to ensure, among other things, that the drug would be available at the FUL price and that the FUL would generate cost savings to the federal government because it would be lower than the reported AWPs. (*Id.*) If the lowest published price appeared to be significantly lower than the next available published price, CMS employees contacted manufacturers to determine if the published price was valid and nationally available. In addition, CMS employees generally would not use a lowest published price if it resulted in a FUL that was not higher than at least three other published prices. (*Id*.) Thus, it would appear, for example, that if defendants Dey and Roxane had reported truthful prices to the publishing compendia for ipratropium bromide, the FUL for that drug would have been lower. The paragraph is otherwise denied, and is not supported by the cited authority.

91. Moreover, FULs are supposed to be set based on the lowest published price, 52 Fed. Reg. 28648 (July 31, 1987), and AWPs were not the lowest of published prices. (3/19/08 Gaston Dep. at 456:10-456:20, Ex. 147; Rox. 56.1 ¶¶ 116-123; 278) Sue Gaston, the CMS employee responsible for setting FULs from April 1991 through February of 2003, testified that CMS "wouldn't have used AWP" when establishing FULs because "[s]etting a FUL using the AWP wouldn't achieve the cost savings." (Id. (3/19/08 Gaston Dep. at 458:15-459:7, Ex. 147); see also id. (5/20/08 Sexton Dep. at 49:13-50:21, 76:20-77:13, Ex. 159) (the CMS employee responsible for setting FULs beginning in 2004 testified that she could not recall ever having set a FUL based

on an AWP). So, if there was a FUL in place, published AWPs could never influence actual payment of the claim because the FUL was always lower than the published AWP.

United States' Response: The United States disputes that if "there was a FUL in place, published AWPs could never influence the actual payment of a claim because the FUL was always lower than the published AWP." The United States' theory of recovery and damages model are not based upon defendants' false price statements causing inflated FULs; rather, the United States asserts that defendants' false price representations caused EAC to be inflated, and thereby caused damages whenever the original reimbursement amount – whether based on EAC, MAC, FUL, or U&C – was higher than it would have been but for the inflated EAC. All or nearly all States would have based reimbursement on EAC had it resulted in a lower amount. (Henderson Common Ex. 24 (Knerr Decl.) ¶18, 19, 24.)

Responding further, pursuant to 42 C.F.R. § 447.332(a)(1)(ii), CMS utilized prices listed in "published compendia" (i.e., AWPs, WACs and Direct Prices) in setting FULs. (Fauci Exhibit 145 (Declaration of Sue Gaston (hereinafter, "Gaston Decl.")), ¶ 6.) The United States does not dispute that FULs were usually based on prices other than AWPs, as the reported AWPs were generally but always higher reported WACs or Direct Prices.

Additional Statements of Material Fact Submitted by the United States In Response to Defendants' Statements of Additional Fact

91.1. No state Medicaid official testified that the pertinent state Medicaid agency or any representative thereof approved the defendants' practice of reporting false pricing information to the compendia. To the contrary, virtually every state Medicaid witness testified that he or she did not approve of the conduct. For example,

91.2. Suzette Bridges of the Arkansas Medicaid agency testified as follows:

Q. The United States alleges in its complaint that the defendants here, Dey, Abbott and Roxane, knowingly reported falsely-inflated AWPs to FDB with the intention of causing the Medicaid Program to pay inflated reimbursements to their customers. In your preparation for the deposition, have you seen any -- any evidence that anybody at DHS approved the reporting of inflated AWPs by either Dey or Abbott or Roxane?
A. No.
MR. REALE: Objection, form. Outside the scope.
MS. MANGIARDI: Objection.
Q. (By Ms. Oberembt) You can answer.
A. No, ma'am.
Q. Have you seen any evidence that Dey or Abbott or Roxane came in and informed anybody at DHS that they were reporting falsely-inflated AWPs to FDB?
MR. REALE: Objection, form.
A. No, ma'am, not that I'm aware of at all.

(12/10/08 Bridges Dep., at 73:9 - 74:8, Henderson Reply Ex. 31.)

91.3. California's pharmacy program director J. Kevin Gorospe testified as follows:

Q. If Abbott Laboratories reported grossly inflated Average Wholesale Prices to First DataBank knowing and intending that those prices would be used by state Medicaid agencies, including Medi-Cal, to pay inflated reimbursements to customers, people who bought Abbott drugs, would you consider that to be deceptive?
MR. COLE: Objection. Form.
A. THE WITNESS: Yes.
Q. Did Dey ever to your knowledge come to the California Department of Health Care Services and tell the Department that it was reporting grossly inflated Average Wholesale Prices on its drugs?
MR. ROBBEN: Objection as to form.
A. THE WITNESS: No.
Q. And if Dey reported grossly inflated Average Wholesale Prices to First DataBank knowing and intending that this would cause state Medicaid agencies to pay inflated reimbursements to customers who bought their drugs, would you consider that to be deceptive?
MR. ROBBEN: Objection as to form.

A. THE WITNESS: Yes.
Q. Likewise, if Roxane Laboratories reported grossly inflated Average Wholesale Prices to First DataBank knowing and intending that those prices would be used by the California Medi-Cal program to pay inflated reimbursements to providers who bought Roxane's drugs, would your consider that to be deceptive?
MS. DANNA: Objection to form.
A. THE WITNESS: Yes.
Q. Did Roxane ever come to the Department to your knowledge and tell the Department that it was reporting grossly inflated Average Wholesale Prices?
MS. DANNA: Objection to form.
A. THE WITNESS: No.
Q. I want to return to Abbott, because I realized that one of my questions – Mr. Cole may have had a legitimate question to the form. If – did Abbott ever come to the department and tell the Department that it was reporting grossly inflated direct prices to First DataBank?
Mr. COLE: Object to the form.
A. THE WITNESS: No. Q. And if Abbott reported grossly inflated direct prices to First DataBank knowing and intending that those prices would be used by Medi-Cal to pay inflated reimbursements to providers who purchased Abbott's drugs, would you consider that to be deceptive?
MR. COLE: Objection. Form.
A. THE WITNESS: Yes.

(12/3/08 Gorospe Dep., at 296:5 - 299:1, Henderson Reply Ex. 32.)

91.4. Mr. Chapman of the Colorado Medicaid agency testified:

Q. Thank you. Are you aware of any drug companies creating marketing plans based on incentivizing pharmacies with Medicaid reimbursement?
A. No.
Q. Have you ever been privy to any communications from any source about drug companies incentivizing pharmacies with Medicaid reimbursement?
A. No.
Q. Does that seem appropriate in your view?
A. No.
MR. KATZ: Objection to form.

MR. BERLIN: Objection to form.
A. No.
Q. (BY MR. ANDERSON) Is there anything that you're aware –

THE COURT REPORTER: I'm sorry. Hold on. Who was objecting on the phone?
MR. BERLIN: Eric Berlin for Abbott.
THE COURT REPORTER: Thank you.
Q. (BY MR. ANDERSON) Is there any information that you're aware of, Mr. Chapman, over your years at Colorado Medicaid that would indicate to you that Colorado Medicaid approved of drug companies incentivizing pharmacies based on Medicaid reimbursement?
MR. KATZ: Objection to form.
A. No.

(12/15/2008 Chapman Dep., at 342:12 - 343:19, Henderson Reply Ex. 4.)

91.5. Cynthia Denemark, the 30(b)(6) witness for the State of Delaware, testified,

Q. Did a representative from any of the defendants in this case ever come to you and suggest that it was -- that they were reporting inflated AWPs to compensate for a dispensing fee that in the State of Delaware that they considered to be too low?
MR. CYR: Objection.
MS. RAMSEY: Objection.
A: I have never had any manufacturer propose that, or manufacturer's representative propose that to me.
Q. Did you ever communicate to any manufacturer that you understood and approved their reporting of AWPs that were two or three or four or five or even ten times higher than actual prices?
MR. CYR: Objection.
MS. RAMSEY: Objection.
A: I would never -- I don't recall ever, and I don't have the opinion that it is a reasonable thing to have an inflated AWP, so I would have never had a conversation stating that I approved of what they were doing.
Q. And what is your opinion of an inflated AWP?
MS. RAMSEY: Objection.
MR. CYR: Objection.

A: I think it is sad commentary on the profession that we have no data element that we can reliably use for ingredient costs so that we can move to reimbursing the professional clinician for their services rendered.

(12/10/2008 Denemark Dep., 485:1 - 486:13, Henderson Reply Ex. 11.)

Q. So it was the understanding of Delaware Medicaid that this was an appropriate way to compensate providers under the Delaware Medicaid Program?
MS. HEALY SMITH: Objection.
A: I wouldn't agree that the Division thought it was appropriate
Q. You didn't think there was anything wrong with it?
A. No, I didn't agree to that either.

(*Id.,* at 379:12 - 380:5.)

91.6. James Parker, the Deputy Administrator of Medical Programs for the Department of Healthcare and Family Services, Division of Medical Programs, testified:

Q. Has either Abbott Laboratories or Dey Labs or Roxane or Boehringer Ingelheim ever come to the State of Illinois and informed the State that its reported AWPs did not reflect accurate prices?
MR. BERLIN: Objection, form.
MR. MALONEY: Objection.
MR. REALE: Objection.
A. THE WITNESS: No.
BY MS. OBEREMBT:
Q. The United States in its complaints against Dey and Abbott and Roxane has alleged that the manufacturers reported falsely inflated AWPs to FDB with the intention of causing the Medicaid program to pay inflated reimbursements to its customers and that they did this for the purpose of increasing the sales to their customers. Has the State of Illinois ever approved of that conduct? MR. REALE: Objection.
MR. MALONEY: Objection.
MR. BERLIN: Objection.
A. THE WITNESS: No.
BY MS. OBEREMBT:
Q. If I told you that Dey and Abbott and Roxane's reported AWPs for certain generics were sometimes three to ten times

higher than the actual sales prices, do you think that was something that Illinois understood and accepted when it established the various reimbursement methodologies we've seen in Exhibit 3?
MR. MALONEY: Objection, form.
MR. REALE: Objection.
A. THE WITNESS: No.
BY MS. OBEREMBT:
Q. If these manufacturers, Dey, Abbott and Roxane, indeed reported prices to FDB in the manner that I've described, knowing and intending that the State Medicaid program would pay inflated reimbursement to providers who purchased those drugs, would you consider that fraudulent?
MR. REALE: Objection, form.
MR. MALONEY: Objection, form.
A. THE WITNESS: Yes.

(11/18/08 Parker Dep., at 76:12 - 78:12, Henderson Reply Ex. 33.)

91.7. Maryland's Joseph Fine testified that Maryland did not approve of the defendants' conduct:

Q. And DOJ 24 is a copy of the United States first amended complaint in In Re: Pharmaceutical Industry Average Wholesale Price Litigation in the United States District Court for the District of Massachusetts. Mr. Fine, if I could ask you to read the first paragraph of this complaint on this first page, just read it out loud.
A. The United States brings this action to recover losses sustained by the Medicare and Medicaid programs as a result of the sustained efforts of the defendants, Dey Incorporated, Dey L.P. Incorporated, and Dey L.P. (collectively 'Dey') to defraud these programs. Over the course of a number of years Dey has reported inflated drug prices knowing that Medicare and Medicaid would rely on those prices to set reimbursement rates for Dey's pharmaceutical products. "Dey's actual sales prices for its pharmaceutical products were and are far less than the prices reported by Dey. By knowingly reporting fraudulently inflated prices - sometimes a thousand percent higher than Dey's actual prices - Dey has ensured that its retail customers and other providers who dispense its drugs receive inflated reimbursement and profits

from Medicare and Medicaid." Dey has used the public fisc as a marketing tool, actively promoting the government-funded spread between, one, its fraudulently inflated prices and, two, its actual sales prices as an inducement to its customers. These efforts have allowed Dey to increase its profits by boosting sales for its drugs."

Q. Thank you. Did Maryland know that Dey was engaging in this conduct?

MR. TORBORG: Objection. Hold on.

MS. MANGIARDI: Objection.

MR. TORBORG: Hold on. This is way outside the scope of my notice and what the foundation can – there's been no foundation that he's even prepared to answer this question.

MS. YAVELBERG: I think it's within the scope and I think he is prepared having been with the State of Maryland for over 20 years to testify about whether Maryland knew of or approved of this conduct.

MR. TORBORG: It's kind of a broad question. I mean, you're asking about all of it as once?

MS. YAVELBERG: Sure.

MR. TORBORG: All of the various elements of this? You're asking about it at once?

MS. YAVELBERG: If he can't answer the question he'll tell us.

MR. TORBORG: I object to this line of questioning as outside the scope of anything that I asked about.

BY MS. YAVELBERG:

Q. Mr. Fine, did the State of Maryland approve of this conduct?

MR. TORBORG: Object to form.

MS. MANGIARDI: Objection.

MR. TORBORG: Alleged conduct.

A. First of all, I've just got to qualify this. The State of Maryland receives drug information from the compendia. We base our price based on that information. Okay? I have as a representative of the State of Maryland no knowledge of this activity.

Q. And if I represent to you that the United States has filed a similar complaint against the Roxane defendants and the Abbott defendants would Maryland have approved such conduct by those companies?

MR. TORBORG: Same objections.

MS. MANGIARDI: Objection.

A. Approval, that would be an outlandish assertion that the company would do this. And it would really cause issues with the state having overpaid based on a fictitious price."

(12/9/08 Fine Dep., at 300:16 - 304:04, Henderson Reply Ex. 46.)

91.8. Margaret Clifford, who was the Medicaid Pharmacy Administrator for the Health and Human Services in New Hampshire from 2001 to 2005, testified as follows:

Q. Now, if a manufacturer, any manufacturer had done that, had come to your agency and said that they were reporting inflated AWPs because they thought New Hampshire's dispensing fees were too low, can you tell me in your opinion whether that is something the Health and Human Services in New Hampshire would have approved of?
MR. KATZ: Objection, form.
A. THE WITNESS: In my opinion, no.
BY MR. HENDERSON:
Q. Did the department give manufacturers the authority to increase dispensing fees?
MR. KATZ: Objection, form.
A. THE WITNESS: No.
BY MR. HENDERSON:
Q. Did the department give drug manufacturers the authority to decide whether dispensing fees were inadequate?
MR. KATZ: Objection, form.
A. THE WITNESS: No.
BY MR. HENDERSON:
Q. Is it fair to say that it is the Health and Human Services that makes decisions about dispensing fees, not drug manufacturers? MR. KATZ: Objection, form.
A. THE WITNESS: Yes.
BY MR. HENDERSON:
Q. Why is that?
MR. KATZ: Objection, form.
A. THE WITNESS: Because we are the ones paying the bill; we should set what we are going to pay.

(10/29/2008 Clifford Dep., at 322:4 - 323:14, Henderson Reply Ex. 50.)

91.9. Aileen Hiramatsu, who was the head of the Hawaii Medicaid Division of the State of Hawaii Department of Human Services from around 2000 to March 2004, testified:

Q. Okay. I have a few other questions. Ms. Hiramatsu, the United States, in its complaint in the federal case, and I'll start with the complaint against the Dey Defendants, the government alleges that Dey knowingly reported falsely inflated AWPs to First DataBank and that they did this with the intention of causing the Medicaid program to pay inflated reimbursements to Dey's customers. And the government alleges that Dey did this for the purpose of increasing the sales of its drugs and Dey's market shares for the drugs. Now, if that were true, if the government's allegations were true, to your knowledge has the State of Hawaii ever approved that sort of conduct?
MR. TOSCANO: Objection to form.
A. THE WITNESS: Have we approved the conduct of the manufacturers reporting inflated AWPs?
BY MR. HENDERSON:
Q. That's correct.
A. No, we would never have approved of such behavior.

* * *

Q. I'm just asking whether this is something that you would have known about had the agency approved of this kind of conduct.
MR. MOORE: Objection; form.
BY MR. HENDERSON:
Q. Or is it outside the scope of your knowledge?
A. I think that's probably outside the scope of my knowledge.
Q. Okay. So are you suggesting that it's possible that somebody else could have approved of that sort of behavior and you would not know about it?
A. Based on what I know of the operations of the division and of the individuals who worked there, I don't believe anybody would approve of such behavior.
Q. Okay. Thank you.
MR. MOORE: Excuse me. Objection; nonresponsive. Move to strike. Go ahead.
BY MR. HENDERSON:

Q. Well, let me try to respond to the objection. Ms. Hiramatsu, based on your experience as an employee of the agency from 1994 through 2007 and based on your experience as head of the Medicaid division from 2000 to 2004, do you have an opinion as to whether or not an employee, an authorized employee of the state Medicaid agency would approve of the type of behavior that I just described?
MR. MOORE: Objection; form.

A. THE WITNESS: Based on my experience with the division, I'd say there was no one there who would have approved of such behavior.
BY MR. HENDERSON:

Q. Now, with regard to the defendant Boehringer, Ingelheim and Roxane, the United States in its complaint against these companies alleges that the Boehringer, Ingelheim, Roxane defendants knowingly reported falsely inflated AWPs to First DataBank and they did this with the intention of causing the Medicaid program to pay inflated reimbursements to their customers, and that these defendants did this for the purpose of increasing the sales of their drugs and for the purpose of increasing their market shares for the drugs.
Again, to your knowledge, has the State of Hawaii ever approved of that sort of behavior with regard to the Boehringer, Ingelheim, Roxane defendants?
MS. LORENZO: Object to form.

A. THE WITNESS: Based on my knowledge of the division, I don't believe anyone would have approved of reporting false information.

(5/2/08 Hiramatsu Dep., at 346:3 - 350:17, Henderson Reply Ex. 67.)

III. MEDICARE

A. November 25, 1991 Final Rule

92. On June 5, 1991, CMS published a proposed rule relating to Medicare Part B's payment for drugs administered incident to a physician's service. The proposed rule stated, "we are proposing that we will instruct all carriers to base payment for drugs on 85% percent of the national average wholesale price of drug (as published in Red Book and similar price listings), but we welcome comments regarding the appropriate discount." (Ex. 160 (56 Fed. Reg. 25792, 25800) (Abbott Ex. 120).) The proposed rule also stated that "the Red Book and other wholesale price guides substantially overstate the true costs of drugs." (*Id.*)

United States' Response: Undisputed, except that the quotations are taken out of context and are therefore incomplete.

93. CMS's proposal to base Medicare Part B drug payment at 85% of AWP for drugs furnished incident to a physician's service was not implemented. Instead, HCFA implemented a payment regulation whereby Medicare Part B payment for multiple source drugs and biologicals was calculated as the "lower of the estimated acquisition cost described in paragraph (b) of this section or the wholesale price that, for this purpose, is defined as the median price for all sources of the generic form of the drug." (42 C.F.R. § 405.517(c), Ex. 161 (56 Fed. Reg. 59502, 59621) (Abbott Ex. 1020).) 42 C.F.R. § 405.517(b) provides the following methodology:

> Payment for a drug described in paragraph (a) of this section is based on the lower of the estimated acquisition cost or the national average wholesale price of the drug. The estimated acquisition cost is determined based on surveys of the actual invoice prices for the drug. In calculating the estimated acquisition cost of a drug, the carrier may consider factors such as inventory, waste, and spoilage.

(*Id.*)

If the providers' billed charge was lower than the estimated acquisition cost or the average wholesale price, Medicare carriers would pay based on the providers' billed amount. (Ex. 155 (Abbott Ex. 309).) This payment methodology reimbursement level was effective as of November 25, 1991 and remained in effect until Congress enacted the Balanced Budget Act of 1997. [The] BBA of 1997 set payment for drugs paid under Medicare Part B at "95 percent of the average wholesale price." (42 U.S.C. § 1395u(o); Pub. L. No. 105-33 § 4556(c), 11 Sat. 251, 463 (1997), Ex. 162 (Abbott Ex. 201).) If the providers' billed charge was lower than the 95 percent of the average wholesale price, Medicare carriers would pay based on the providers' billed amount. (Ex. 163 (Abbott Ex. 529).)

United States' Response: The statements that "42 C.F.R. § 405.517(b) provides the following methodology" and "[t]his payment methodology . . . remained in effect until Congress enacted the Balanced Budget Act of 1997" are not entirely correct. The above-quoted language of section 405.517(b) was promulgated in 1991 and remained in effect until January 1, 1998, the effective date of the 1997 BBA, when Medicare carriers began paying at 95% of AWP. Effective January 1, 1999, the regulation was changed to read, "(b) Payment for a drug or biological

described in paragraph (a) of this section is based on the lower of the actual charge on the Medicare claim for benefits or 95 percent of the national average wholesale price of the drug or biological." 63 Fed. Reg. 58,814, 58905 (Nov. 2, 1998). The United States notes, however, that at the time of the promulgation of the 1991 version, the agency had not established any dispensing fees for Part B drugs. In approximately 1994, HCFA established a $5.00 dispensing fee for inhalation therapy drugs. And see the United States' response to SOAF No. 98 below.

94. The preamble to the November 25, 1991 final rule acknowledges that "many drugs could be purchased for considerably less than 85 percent of AWP – particularly multi-source drugs." (56 Fed. Reg. 59502, 59524, Ex. 164 (Abbott Ex. 301).)

United States' Response: The United States does not dispute that the Federal Register publication contains the quoted language. However, the quotation is out of context and therefore incomplete.

95. In a section titled "Effects of Separate Payment for Drugs," the preamble to the November 25, 1991 final rule contained the following language:

> Under our *final policy*, carriers will be instructed to base payment for drugs on the lower of estimated acquisition cost or the national average wholesale price of the drug as *published in the Red Book and similar price listings*.

(*Id*. at 59615 (emphasis added), Ex. 164 (Abbott Ex. 301 at Page 18).)

United States' Response: Undisputed.

96. The preamble to the November 25, 1991 final rule also contained the following language:

> f. *Low osmolar contrast media* (LCOM). Divergent payments exist among carriers for LOCM, also known as non-ionic contrast material, for radiological studies. We will pay separately for LOCM if it is used for patients with specified characteristics under the *standard methodology for payment of drugs generally. That is, we will base payment on the lower of estimated acquisition cost or the*

> *published* wholesale price of the drug. The estimated acquisition costs will be determined based on carrier surveys of actual invoice prices paid by physicians.

(*Id*. at 59509 (emphasis added), Ex. 164 (Abbott Ex. 301 at Page 24).)

United States' Response: Undisputed.

97. In October 1991, the OIG provided comments to CMS noting that the preamble to the 1991 regulation "uses the term 'published wholesale price' while the regulation[']s text uses the term 'national average wholesale price.'" (Ex. 165 (HHD816-0025).) OIG stated, "We believe separate terminology may lead to confusion." (*Id*.)

United States' Response: Undisputed.

98. On or around March 14, 1994, the Director of the CMS Office of Payment Policy issued a memorandum to all CMS Regional Administrators that set forth, among other things, how carriers should determine the AWP for purposes of Medicare Part B's payment for drugs. (Ex. 166 (Abbott Ex. 114).) That memorandum included the following language:

> Determination of AWP – To determine AWP, calculate the median price of the generic form of the most frequently administered dosage of the drug as reflected in sources such as the Red Book, Blue Book, or Medispan. . . .
>
> * * *
>
> Additional Costs – Section 405.509 of the regulations permits the carriers to consider additional costs when determining the estimated acquisition costs of a drug. We have been told that for some drugs, notably chemotherapy drugs, physicians may incur additional costs related to the drugs. These costs have been described as overhead costs and include storage, waste, spoilage. breakage, and handling. Some physicians do not incur costs for handling drugs in their offices because they use a drug dispensing service. In addition to the estimated acquisition costs, consider allowing an additional fee for the overhead of handling or dispensing drugs. However, in no case can the payment for the drug plus a dispensing fee exceed the AWP for the drug.

(*Id*. at HHC903-0914 – 15.)

United States' Response: Undisputed. Responding further, the United States observes that the quoted language beginning "Additional costs" concerns the agency's unsuccessful effort to determine estimated acquisition costs through surveys, as contemplated in the then-effective regulation at 42 C.F.R. § 405.517(b). The author of the memorandum and Director of the CMS Office of Payment Policy was Charles Booth. Abbott and other members of the pharmaceutical industry undertook lobbying efforts to kill the effort to obtain reliable acquisition cost information. Specifically, in June 1994, Abbott's Washington Office employee Dolly Hanrahan forwarded a memo to Alan Mackenzie, with ccs: to Abbott's Chief Financial Officer G. Coughlan and D. Landsidle (a Divisional Vice President), wherein she described the work she had been doing on Abbott's behalf, together with other manufacturers and industry members. Ms. Hanrahan wrote:

> I have been in contact with the Washington representatives of Bristol-Myers Squibb, Amgen, Zeneca, and the American Society for Clinical Oncology (ASCO), regarding the memorandum from Charles Booth, Director, Office of Payment Policy at HCFA, to the Medicare carriers regarding changes in payment for certain drugs. Everyone shares our concerns over the survey HCFA is conducting on the acquisition price versus the average wholesale prices on certain drugs. ASCO issued a memorandum to its members advising them that compliance with the survey is voluntary and that physicians are under no legal obligation to complete the survey issued by the carriers. HCFA is not pleased with ASCO's guidance to physicians. ASCO is working directly with the Office of Management and Budget (OMB) to essentially kill the survey based on the grounds that HCFA has not followed administrative procedures. OMB may stop the survey but this would only serve to buy more time; HCFA would simply resubmit the survey following appropriate procedures. . . .
> ASCO has asked us to discuss other ways in which physicians might be helpful, and to advise them of our ideas.
>
> The Washington representatives are prepared to meet if we all determine the best course of action is to do so. Please think about what our next steps should be and let me know how to proceed.

(10/15/07 Landsidle Dep., at 78:3-22; 79:1-15, and Deposition Exhibit 14, Henderson Reply Ex. 68). The Office of Management and Budget eventually disapproved the proposal to conduct surveys. (10/29/2007 Booth Dep., at 310:22 - 311:15, Henderson Reply Ex. 19.)

B. The Balanced Budget Act of 1997

99. Section 4456(c) of the Balanced Budget Act of 1997 includes the following provision:

> (C) STUDY AND REPORT - - The Secretary of Health and Human Services shall study the effect on the average wholesale price of drugs and biologicals of the amendments made by subsection (a) and shall report to the Committees on Ways and Means and Commerce of the House of Representatives and the Committee on Finance of the Senate the result of such study not later than July 1, 1999.

(Pub. L. No. 105-33, Section 4456(c), 11 Stat. 251, 463 (1997).)

United States' Response: The United States admits that the Defendants have correctly, but selectively, quoted one sub-section of the Balanced Budget Act of 1997's section titled Reimbursement For Drugs And Biologicals. The entirety of the section is the best evidence of its content. Sections (a) and (b) omitted by the defendants, which include specific provisions dealing with dispensing fees and reference "average wholesale price" but not any of the compendia, state:

> SEC. 4556. REIMBURSEMENT FOR DRUGS AND BIOLOGICALS.
> (a) In General.--Section 1842 (42 U.S.C. 1395u) is amended by inserting after subsection (n) the following new subsection:
> (1) If a physician's, supplier's, or any other person's bill or request for payment for services includes a charge for a drug or biological for which payment may be made under this part and the drug or biological is not paid on a cost or prospective payment basis as otherwise provided in this part, the amount payable for the drug or biological is equal to 95 percent of the average wholesale price.
> (2) If payment for a drug or biological is made to a licensed pharmacy approved to dispense drugs or biologicals under this part,

> the Secretary may pay a dispensing fee (less the applicable deductible and coinsurance amounts) to the pharmacy."
> (b) Conforming Amendment.--Section 1833(a)(1) (42 U.S.C. 1395l(a)(1)), as amended by sections 4315(b) and 4531(b)(1), is amended-- (1) by striking ``and (R)" and inserting ``(R)"; and (2) by striking the semicolon at the end and inserting the following: ``, and (S) with respect to drugs and biologicals not paid on a cost or prospective payment basis as otherwise provided in this part (other than items and services described in subparagraph (B)), the amounts paid shall be 80 percent of the lesser of the actual charge or the payment amount established in section 1842(o)"

Responding further, the United States observes that Abbott lobbied vigorously to oppose language in the 1997 BBA that would have given the Secretary of HHS greater authority to adjust Medicare drug payments to more closely reflect acquisition costs. On February 10, 1997, Abbott's Director of Washington Affairs Cynthia Sensibaugh wrote to various Abbott employees, including in house counsel Mark Barmak, an Alternate Site Reimbursement Specialist, stating that:

> [T]he President included a provision in his FY 1998 budget proposal that would base the Medicare reimbursement for outpatient drugs on acquisition cost rather than AWP. An industry meeting to discuss strategy with regard to this issue has been tentatively scheduled for Thursday, February 20. We would like to get your thoughts on this issue before the meeting. I will call to set up a conference call on Friday or Monday.

(Henderson Reply Ex. 69.)

In his "Monthly Highlights," Abbott's Divisional Vice President David Landsidle reported that in May and June of 1997, he met with members of Congress and their staff to discuss "House and Senate proposals which would change reimbursement for Medicare to 95% of average wholesale price (AWP)." (Landsidle Dep. Exhibit 23, Henderson Reply Ex. 68; Henderson Reply Ex. 70.) On June 5, 1997, Mr. Landsidle, wrote to key Abbott employees including HPD Renal Division head Loreen Mershimer, HPD Alternate Site Reimbursement Manager Michael Heggie,

in-house attorney and head of Abbott's Government Affairs program, Mark Barmak, to explain his lobbying efforts to keep out of the bill proposals by the House that would permit HHS to determine reimbursement rates drug-by-drug. He explained:

> I spoke with Congressman Christensen during the mark up. He is pleased we have come so far by dropping acquisition cost, but wants to go further. We will see what can be done between now and full Ways and Means markup on Monday. Issues under review include having the provision reading "AWP minus 5%" rather than no more than 95% of AWP as specified by the Secretary" since "no more than" means that a reduction of more than 5% is permissible. *Congress should not permit HHS to determine reimbursement rates drug by drug.*
> Also, we have checked with the House Commerce Committee which also marks up its Medicare bill next week. It, too, has dropped the acquisition cost and gone with the same "no more than 95% of AWP."

(Landsidle Dep. Exhibit 21, Henderson Reply Ex. 68 (emphasis supplied.) *See also* Henderson Reply Ex. 71 (setting forth proposed House language)).

In 1997, in the months before passage of the Balanced Budget Act of 1997, Pub. L. 105-33, 111 Stat. 462-463 (August 7, 1997), Abbott actively lobbied members of the House of Representatives to limit the reimbursement language in the bill to require simply that reimbursement be set at "95% of AWP," and to strip any discretion on the subject from the Secretary. On June 9, 1997, Abbott's Divisional Vice President David Landsidle wrote a second memorandum to Abbott President Duane Burnham asking permission to hire an outside lobbyist, Nancy Taylor, from Greenberg Traurig. One of the statements in Landsidle's memorandum was that "Reimbursement of Medicare drugs is the Washington Offfices (sic) top priority. His memorandum also stated:

> There is language in the House Ways and Means and House Commerce Committee's Medicare bills that change the way

> Medicare reimburses drugs. Rather than reimbursing according to average wholesale price (AWP) as it is now, the bill would provide reimbursement 'at no more than 95% of AWP, as specified by the Secretary (of HHS).' This language is troubling because it could be, and is likely to be, read as a maximum and would allow the Secretary to establish other criteria as long as it is no more than 95% of AWP (e.g. actual acquisition cost). We are working to change this language to provide that reimbursement would be only at 95% of AWP with no discretion left to the Secretary. This should address as well the issue raised in our South Carolina lawsuit (i.e. the authority of HCFA and its carriers to be creative in reimbursement).
> I would like to retain Nancy Taylor with the lobby firm of Greenberg Traurig. . . . The cost would be in the $10,000 to $20,000 range. . . . With reimbursement for Lupron, Calcijex and Abbokinase at issue, hiring Greenberg Traurig could be most useful. Reimbursement of Medicare drugs is the Washington Offfices (sic) top priority. . .

(10/15/2007 Landsidle Dep., at 228:3 - 229:18, and Deposition Exhibit 20 (emphasis supplied), Henderson Reply Ex. 68.) According to Mr. Landsidle, at the time he wrote the June 9, 1997, memorandum, there was a distinct possibility that a bill might pass that would afford the Secretary of HHS discretion to set Medicare reimbursement at rates below 95% of AWP, since the House had at that point already included the discretion language. Mr. Landsidle, sensing that Abbott needed another "soldier on Capitol Hill," recommended the hiring of Ms. Taylor. (*Id.,* at 228:3 - 229:18.)

The hiring of Ms. Taylor as a lobbyist to advance Abbott's interest in stripping the Secretary of discretion to specify or set reimbursement for drugs was approved by Abbott's then Vice President of Abbott's Hospital Products Division ("HPD"), Kris Kringel. Abbott HPD's drug Calcijex, which accounted for a full one-third of the HPD's profits, was noted by Mr. Landsidle as one of Abbott's drugs that could be adversely affected in a significant way. A Medicare reimbursement statute that provided for reimbursement at 95% of AWP, with no discretion to the

Secretary was important to HPD, among other divisions in Abbott. (10/15/07 Landsidle Dep., at 233:21 - 234:11, 235:20 - 236:3, and Deposition Exhibit 20, Henderson Reply Ex. 68; Henderson Reply Ex. 72.)

Abbott itself sought to submit to Senators its own recommendations for markups to the Medicare reimbursement legislation. (Henderson Reply Ex. 73.)

According to Mr. Landsidle, it was imperative for Abbott to hire Ms. Taylor "to try and get a solution that did not allow discretion to the Secretary." As Mr. Landsidle testified:

> Q. Did you have serious concerns, in or around June of 1997, that Congress ultimately might adopt a Bill on Medicare drug reimbursement that would have given discretion to the Secretary to set reimbursements at below 95% of AWP.
> MS TABACCHI: Object to the form.
> A. THE WITNESS: Because the House had already included language, you have to assume that that was in play. It was a distinct possibility.
> BY MR GOBENA:
> Q. So it was imperative, then, to hire Ms. Taylor in order to put as many resources as possible into blocking that language from being implemented; correct?
> MS TABACCHI: Object to the form.
> A. THE WITNESS: It was imperative to hire her to try and get a solution that did not allow discretion to the Secretary.

(10/15/07 Landsidle Dep., at 229:9 - 230:5, Henderson Reply Ex. 68.) In a memorandum to Abbott in-house counsel Mark Barmak, Mr. Landsidle explained the impact of the competing House and Senate proposals concerning the Medicare reimbursement issue in the budget reconciliation bills. He explained to Abbott's Government Affairs head and in-house counsel that:

> The House and Senate are expected to vote next week on the budget reconciliation bills. The bills will pass and the conference committee will begin work the week of July 7. The conference could take anywhere from 2 to 4 weeks. The Congress plans to vote on the conference bill before the August 2 start of the summer recess.

> Regarding the Medicare reimbursement issue, the House has a good provision although we need to add "specific" drug or biological. The Senate provision is not good. It says:
>
> - payment could not exceed 95% of the AWP, as specified by the Secretary
>
> * * *
>
> - the amount payable is limited by an annual CPI adjustment
> - an HHS study is required to determine the AWP or other appropriate price of outpatient prescription drugs which then could be used to "further adjust payment amounts for outpatient prescription drugs.

(Henderson Reply Ex. 72 (emphasis supplied).) To fight the adoption of the Senate language that granted discretion to the government, Mr. Landsidle recommended in the memorandum that Abbott have its CEO come to Washington to meet with members of Congress. Mr. Landsidle explained:

> Abbott has a lot at stake in the reimbursement fight. I do not want to feel, or having others feel, we did not do everything possible to win in conference. Duane [Burnham, Abbott's CEO in 1997] could help. I can not (sic) get an appointment with [Congressman] Archer during conference. With Duane I can. A visit by him increases the importance to Abbott to the issue, which congressmen understand. . . [A] CEO adds a good deal of clout.

(*Id.*) Mr. Landsidle cautioned that bringing Mr. Burnham to Washington and involving him in the lobbying effort did have a downside, which was that Abbott's interest in the AWP fight was "profit motivated." He cautioned: "[t]he downside is Duane being exposed to having to defend our position which is profit motivated. There is no way to avoid that fact." (*Id.*)

On June 30, 1997, Mr. Landsidle wrote to Abbott's CEO about his involvement in the lobbying efforts. First, he laid out for Abbott's CEO Abbott's view of the problems with the

Senate version of the legislation governing Medicare reimbursement, and the reasons why Abbott should support the House version. He wrote:

> The House and Senate have passed different changes to how Medicare reimburses drugs (i.e. Lupron and [HPD's] Calcijex). The basic change is that future reimbursement will be 95% of average wholesale price (AWP) rather than full AWP. However, the Senate bill has additional language we oppose. . . .
>
> - The Senate bill says that the amount reimbursed can not (sic) exceed the May 1, 1997 amount increased annually by the CPI. The House has no change in CPI language.
>
> - The Senate bill calls on the Secretary of HHS to do a study of AWP and report back to Congress within 6 months. This gets HHS looking at prices. The House bill has no such language.

(Henderson Reply Ex. 74.) In that same June 30, 1997, memo, Mr. Landsidle explained to Mr. Burnham what Mr. Burnham should say to the members of Congress with whom Mr. Burnham would speak directly:

> I [Mr. Landsidle] am putting together calls between you and Ways and Means Chairman Archer (R-Tx) and Congressman Denny Hastert (R-IL). Both will be House conferrees when the House and Senate meet to reconcile differences. Your message to both men is simple:
>
> - Abbott thinks the House language providing for Medicare reimbursement of drugs at 95% of AWP, effective January 1, 1998, is much better than the Senate language. . . .
>
> - Abbott asks that you fight to retain the House language in the conference committee and that Abbott joins you in fighting for their language.

(*Id.*; *see also*, Henderson Reply Ex. 75 (setting forth Senate language proposal).) After Congress adopted the House version of the bill with the language setting Medicare reimbursement at "95% of AWP" without affording the Secretary any discretion to adjust reimbursement rates, Abbott's

CEO wrote to Congressmen Archer and Hastert, thanking them for their efforts. (Henderson Reply Ex. 76; Henderson Reply Ex. 77.)

After not being able to speak with Congressman Hastert, Abbott's CEO Mr. Burnham wrote:

> Congratulations for putting together the balanced budget legislation, an accomplishment of truly historic importance. Your personal efforts helped create a package beneficial to all Americans. I specifically want to thank you for holding the House Medicare drug reimbursement language in conference. Although we never were able to hook up together by telephone, Abbott appreciates all you did to address our concerns. We, and Illinois, were fortunate to have you negotiate such important legislation.

(Henderson Reply Ex. 77.) After speaking with Congressman Archer, Abbott's CEO Mr. Burnham wrote to Congressman Archer:

> I want to express our gratitude for what you accomplished with the Medicare drug reimbursement provision. When we spoke on the telephone you said you intended to hold the House language in the conference committee, and you did. Your language was clearly superior to the Senate's and Abbott thanks you for convincing the rest of the conferees. I know you had far bigger issues on the agenda. Taking the time to call me and discuss our concerns was greatly appreciated.

(Henderson Reply Ex. 76.) In October of 1997, Mr. Landsidle reported to Abbott's general counsel, Mr. de Lasa that he met with member of congressional staffs to "ensure that the Health Care Financing Administration correctly interprets this summer's Medicare reimbursement law." (Henderson Reply Ex. 78.)

100. To comply with Section 4556(c) of the Balanced Budget Act of 1997, Donna Shalala, Secretary of the Department of Health and Human Services, provided a "Report to Congress on The Average Wholesale Price For Drugs Covered Under Medicare" in 1999. (Ex. 167 (HHC902-0801 – 18).) In her report, Secretary Shalala compared the increase in AWPs reported

by First Databank with inflation. (Id. at HHC902-804.) Ms. Shalala report included the following language:

> The AWP is not a well-defined concept nor is it regulated in any way. OIG reports that AWP is set by manufacturers as a suggested price and published in various commercial sources. However, it is not truly an average of wholesale prices because very few purchasers actually pay this amount
>
> * * *
>
> Conclusions are further obfuscated by the OIG finding cited earlier in this report that, as an unregulated, suggested price, typically set by the manufacturer, the AWP bears no consistent or predictable relationship to the prices actually paid by physicians and suppliers to drug wholesalers in the marketplace.

(*Id*. at HHC902-0803, 0809.)

United States' Response: The United States admits that the Defendants have correctly, but selectively, quoted two small portions of a much longer report. The defendants have omitted six pages of materials between the two quoted sections. The United States notes that the quoted sections of the report are based upon an OIG study of a small sample of reported AWPs for only 22 drugs for which reimbursement is made by Medicare, as set forth in the report immediately following the first portion of the quotation above.

101. T. Mark Jones provided the following testimony:

> Q. Quote, "During that meeting, we were shocked by certain statements made by certain HCFA officials concerning their understanding that the term AWP had never been legislatively or administratively defined by the Federal Government," close quote.
> Was that statement made during your September 1995 meeting?
> A. I remember it being said that AWP isn't defined. That's how I remember these. I don't remember it being legislatively or administratively defined.

Q. The people who were making that statement, they were the people at HCFA who were responsible for administering the Medicare and Medicaid programs. Correct?
A. To the best of my recollection, I remember it being Sheree Kanner who was the general counsel for HCFA.
Q. You remember it was Ms. Kanner who said that AWP –
A. That's how I remember it, yes.
Q. And as the office of general counsel, you understand that Ms. Kanner was HCFA's lawyer. Correct?
MR. BREEN: Objection to form.
A. THE WITNESS: Yeah. I guess.
BY MR. COOK: Q. Did you disagree with Ms. Kanner about whether AWP had ever been legislatively or administratively defined by the Federal Government?
A. I don't remember if I had any dialogue with her over it.
Q. Did Mr. Lavine disagree with Ms. Kanner at this meeting?
A. I don't remember it being a big dialogue. I think it was a statement that I remember.
Q. Do you remember anybody at that meeting disagreeing with Ms. Kanner that AWP had never been legislatively or administratively defined by the Federal Government?
A. No.

(3/19/08 Jones Dep. at 551:9-553:8, Ex. 168.)

United States' Response: Undisputed but clearly irrelevant.

102. CMS instructed its carriers in its regulations implementing the Balanced Budget Act of 1997 to set payments at 95 percent of the national average wholesale price "as reflected in sources such as the Red Book, Blue Book, or Medispan." (Ex. 169 (63 Fed. Reg. 58814).) CMS's regulations stated that "it is clear that the AWP is higher than the amount typically paid for drugs by physicians" and that "significant discounts from AWP are common." (Ex. 169 (63 Fed. Reg. 58849-50).)

United States' Response: The statement is incorrect. The regulation promulgated in the Federal Register publication referenced above (42 C.F.R. § 405.517) provided in part as follows:

> (b) Payment for a drug or biological described in paragraph (a) of this section is based on the lower of the actual charge on the Medicare claim for benefits or 95 percent of the national average wholesale price of the drug or biological.

> (c) For multiple-source drugs and biologicals, for purposes of this regulation, the average wholesale price is defined as the lesser of the median average wholesale price for all sources of the generic forms of the drug or biological or the lowest average wholesale price of the brand name forms of the drug or biological.

63 Fed. Reg. 58,905 (Nov. 2, 1998). The United States does not dispute that the preamble to the regulation contains the language quoted by the defendants.

103. And in 2001, GAO publicly announced that the "term AWP is not defined in law or regulation, so the manufacturer is free to set AWP at any level, regardless of the actual price paid by purchasers." (Ex. 170 at 4 (GAO Report, "Medicare Part B Drugs: Program Payments Should Reflect Market Prices").)

United States' Response: Disputed in part because defendants mischaracterize the statement by asserting that the quoted language was "publically announced," when in fact, and in context, the statement of William J. Scanlon, GAO's Director of Health Care Issues, was provided for purposes of a congressional hearing, and his statement also noted that "the actual price that providers pay for Medicare part B drugs is often not transparent." Further, the United States disputes the statement as inadmissible to the extent the defendants' quotation suggests that Mr. Scanlon intended to interpret law or convey a legal conclusion. *See United States v. Lachman*, 387 F.3d 42, 54-55 (1st Cir. 2004). The statement is also incomplete in that it omits Mr. Scanlon's observations that:

> Our study on Medicare payments for part B drugs shows that Medicare pays providers much more for these drugs than necessary, given what the providers likely paid to purchase these drugs from manufacturers, wholesalers, or other suppliers. . . .
>
> In our view, it should be a principle of Medicare payment policy to pay for each service appropriately and not to rely on overpayments for some services to offset inadequate payments for complementary services.

(*Id*., at 12) Finally, the United States notes that the GAO Statement was presented in the context of congressional hearings that eventually lead to the reforms set forth in Title III of the Medicare Modernization Act, entitled, "Combating Waste, Fraud, and Abuse." Pub. L. 108-173, Title III.

C. Federal Testimony On The Meaning Of AWP

104. Numerous federal CMS and OIG officials testified that CMS understood that the term AWP referred to prices published in the drug compendia. For example:

Defendants' Statement [104](a): Bruce Vladeck served as the CMS Administrator from 1993-97. Dr. Vladeck testified regarding how CMS interpreted the term AWP:

> Q. And the AWP in that legislation, did you understand that in the same way you understood AWP in the regulation from 1992?
> A. Yes.
> MS. BROOKER: Objection. Form.
> Q. And so that would refer to a published average wholesale price. Correct?
> A. That was our understanding of it, yes.

(5/4/07 Vladeck Dep. at 278:18-279:03, Ex. 39.)

United States' Response: The United States does not dispute that Dr. Vladeck served as the HCFA Administrator from May 1993 to September 1997, or that he testified as quoted. Otherwise the statement is disputed inasmuch as Dr. Vladeck did not offer testimony as to how CMS interpreted the term AWP; and he was not a Rule 30(b)(6) designee on behalf of the agency. (5/4/07 Vladeck Dep., at 31:9-20, Henderson Reply Ex. 22.) The statement is further disputed to the extent defendants are suggesting that Dr. Vladeck believed, or CMS agreed, that an AWP could be any number a manufacturer chose to report regardless of actual acquisition costs. To the extent the testimony is viewed as expressing an interpretation of law, it is irrelevant and inadmissible. *United States v. Lachman*, 387 F.3d 42, 54-55 (1st Cir. 2004).

Further answering, as detailed below, numerous federal officials testified that they understood AWP to mean what it says. For example, Thomas Gustafson, a longstanding CMS policy official, testified as follows:

> Q. How did the agency interpret the statute in this particular instance?
> A. I think it's well-known. We used average wholesale price in the Red Book as a reflection of average wholesale price as called for by the statute.

(12/17/2007 Gustafson Dep., at 258:3 - 258:7, Henderson Reply Ex., 94.) And see responses to Paragraphs 104(b), 104(e), and 108 below.

Defendants' Statement [104](b): Nancy-Ann DeParle served as CMS Administrator from 1997-2000. (5/18/07 DeParle Dep. at 54:6-7, 55:20-56:1, Ex. 66.) Ms. DeParle testified regarding how CMS interpreted the term AWP:

> Q. So this was issued just as Congress was essentially taking out of HCFA's hands the discretion to use some measure other than average wholesale price --
> MS. YAVELBERG: Objection to form.
> Q. -- to pay for drugs; correct?
> A. The BBA specified how drugs were to be reimbursed.
> Q. And that was to be reimbursed at 95 percent of the average wholesale price; correct?
> A. Yes.
> Q. And the agency interpreted that to refer to the prices published in the Red Book and Blue Book; correct?
> MS. YAVELBERG: Objection; form.
> A. Yes.

(*Id*. at 130:19-12.)

United States' Response: Disputed for the reasons stated in response to ¶ 104(a) above. The United States admits that Ms. DeParle served as the Administrator of HCFA (now known as CMS) from October or November 1997 to September or October 2000, and that she testified as quoted. Ms. DeParle also testified that she understood the prices published by Red Book and Blue

Book to reflect wholesale prices paid in the marketplace, not prices which were set or controlled by drug manufacturers:

> Q. This is Sarah Reid again. And I only have a few questions. You had testified not too long ago your belief that when you started as administrator that AWP reflected an actual average price. Do you remember that testimony?
> MR. HAVILAND: Can counsel bring her voice up? It's real hard to hear on the phone. I apologize for interjecting.
> Q. Do you recall that's the testimony that you gave to Mr. Haviland?
> A. I thought average wholesale price meant average wholesale price, yeah.
> Q. An actual price. That AWP was an actual price.
> A. I don't know that I would use the word actual. What I meant was that I thought that the Red Book and the Blue Book had the wholesale prices that were paid out there in the marketplace and that's what it's an average of. I guess that's actual.

(12/5/07 DeParle Dep., at 684:17-685:15, Henderson Reply Ex. 79) She also testified:

> Q. And do you recall the HHS OIG report, one of those that was shown to your earlier today, indicated that it was the drug company that set the AWPs that were published by those publications?
> A. You know, I'm sorry. It's been a long day. I don't remember that precisely.
> Q. That's fine. Was that your understanding during the time you were HCFA administrator that the AWPs that were published in those publications were in fact set and controlled by the drug manufacturers?
> A. No.

(*Id*., at 659:15- 660:5).

Defendants' Statement [104](c): Thomas Scully served as CMS Administrator from May 2001 through January 2004. (5/15/07 Scully Dep. at 97:12-15, 50:8-13, Ex. 64.) Mr. Scully testified regarding how CMS interpreted the term AWP:

> Q. And was it you understanding that the, that the AWP that CMS was using as the benchmark for reimbursement was the AWP that was published in the compendia?
> A. For the most part, it was my understanding that the standard practice was that 95 percent of AWP was the AWP that was published in the Red Book.
> Q. And that's what you understood the law and regulations to require?
> A. That's what I understand at the time. At the time, that's what I believe the law and regulations required.

(*Id*. at 105:17-106:06.)

Mr. Scully also testified that AWP is "air," "it's nobody's fault, it's a stupid policy." (Id. at 195:3-5.) Mr. Scully provided the further testimony:

> I don't blame anybody for doing what they did. The government created stupid incentives. But it was an insane policy. And so, understanding it from both sides, I was determined to fix.

(7/13/07 Scully Dep. at 493:14-18, Ex. 65.)

United States' Response: The United States does not dispute that Mr. Scully testified as quoted. United States disputes the materiality of the evidence because Mr. Scully's testimony does not purport to represent the agency's interpretation of its regulations, and is discussing what the agency's practice was with regard to the source of information regarding AWP rather than a definition of a legal term. To the extent he testified concerning the meaning of a statute or regulation, the testimony is irrelevant. *See United States v. Lachman*, 387 F.3d 42, 54-55 (1st Cir. 2004).

Defendants' Statement [104](d): Thomas Scully testified regarding the definition of AWP set forth in the United States' Complaints in the DOJ Actions:

> Q. Okay. Now, this was a complaint that was signed the 22nd day of August, 2006, and on paragraph 40, in the first sentence, it says, AWP is used to refer to the price at which a

pharmaceutical firm or a wholesaler sells a drug to a retail customer, who then administers it to a patient; do you see that?
A. Yes.
Q. That's not what AWP was viewed as, that's not the view of CMS as to what AWP was, is it?
MR. NEAL: Objection as to from.
By MR. ESCOBAR:
Q. Is it?
MR. NEAL: This is not a 30(b)(6), this is not a 30 (b)(6) deposition. You can answer.
A. No, I don't think that's what AWP is commonly considered to be, I think that's an inaccurate description.
Q. In fact, that's a completely inaccurate statement of AWP; right?
MR. NEAL: Objection as to form.
A. I think it's probably a poor description, yes.
Q. Because it's not accurate?
A. Yes.

(7/13/07 Scully Dep. at 709:20-711:02, Ex. 65.)

* * * *

Q. All right. Have you ever used average wholesale price to refer to the price at which a pharmaceutical firm or a wholesaler sells a drug to a retail customer?
A. No.
MR. GOBENA: Object to the form.
Q. Have you ever heard anybody else use AWP to refer to the price of which a pharmaceutical firm or a wholesaler sells a drug to a retail customer?
MR. GOBENA: Object to the form.
A. No.

(*Id*. at 900:16-901:06.)

United States' Response: Undisputed that Mr. Scully testified as quoted. Otherwise disputed for the reasons stated above in response to ¶¶ 104(a) and 104(c) above.

Defendants' Statement [104](e): Kathleen Buto, Director of the Bureau of Policy Development, played a central role in drafting November 25, 1991 final rule. (9/12/07

Buto Dep. at 50:10-52:2, Ex. 171.) Ms. Buto testified regarding what CMS by the use of the terms "national average wholesale price" in the November 25, 1991 final rule:

> Q. . . . Is it fair to say, Ms. Buto, that the intent of CMS in drafting this provision with respect to average wholesale price was to refer to the prices that are found in Red Book and similar price listings?
> A. Yeah. The intent, though, unfortunately, which was never really achieved, was that was the fallback if the agency couldn't come up with estimated acquisition cost. The agency never really came up with estimated acquisition cost.
> Q. There were two possibilities for determining the payment amount, one was estimated acquisition cost. If you were not able to find that for a particular drug then it would be reimbursed under the intent of your regulations by virtue of the average wholesale price as published in Red Book and similar price listings, correct?
> A. Yes. That's certainly the result. . . .
>
> * * * * *
>
> Q. But if we used the average wholesale price method it would be based on what was published in the Red Book, correct?
> A. Yes. That was made clear later in one of the other documents, that it was based on the published. But in the – I think in the original description they didn't refer to published.

(*Id*. at 272:3-22, 306:2-81.)

United States' Response: The United States disputes the statement that Ms. Buto "played a central role in drafting November 25, 1991 final rule" as unsupported by the testimony cited, which, at best, states only that Ms. Buto was the Director of the Bureau of Policy Development at the time and that, generally, that any regulations relating to the reimbursement of prescription drugs drafted during the period would have been drafted by that Bureau. The United States does not dispute that she was involved in the rulemaking. (9/12/07 Buto Dep., at 253:3 - 14, Henderson Reply Ex. 21) The United States also disputes the statement as incomplete, in that Ms. Buto's

testimony on its face differentiates between her understanding of the regulation's intent and the "result," and does not purport to represent the agency's interpretation of its regulations. In addition, insofar as her testimony is construed as relating to the meaning or intent of the regulation, it is irrelevant. *See* United States v. Lachman, 387 F.3d 42, 54-55 (1st Cir. 2004), and the United States' response to SOAF No. 104(a) above. Ms. Buto also testified, when asked about the specific language in the regulation,

> Q. . . . And in that sentence in your final rule the reference to national AWP was to what?
> A. Say that again.
> Q. The reference to the term AWP in this regulation was referring to what?
> A. Well, it sounds like they're -- I guess the thing that I'm stuck on is that it's defined as a median price for all sources of the generic form of the drug. It doesn't seem to address the brand where there is no generic substitution. The national AWP is a median price for all sources of the generic form of the drug.
> Q. My question I think was a little simpler one than that.
> A. Okay. Sorry.
> Q. What does AWP mean in that language?
> A. Average wholesale price? Is that what you mean?
> Q. Yes. Does it refer to the prices in Red Book and other compendia?
> A. It doesn't seem to.
> Q. It does not explicitly there, correct?
> A. It's not explicitly here.

(9/12/07 Buto Dep., at 266:2 - 267:2, Henderson Reply Ex. 21)

Defendants' Statement [104](f): Charles Booth, former Director of CMS's Office of Payment Policy, testified regarding how CMS interpreted the term AWP:

> Q. During this time period from 1991 to 1997 what was your understanding of what AWP referred to?
> A. AWP was what the manufacturers chose to put in the compendia.
> Q. At any time in this time period did you understand AWP to refer to a calculated average of wholesale prices that were charged to physicians or other purchasers of these products?

A. No.

(4/23/07 Booth Dep. at 518:10-18, Ex. 172.)

United States' Response: The United States does not dispute that Mr. Booth testified as quoted. The United States disputes the relevance and admissibility of the testimony for the reasons stated in response to ¶¶ 104(a) and 104(c) above.

Defendants' Statement [104](g): Robert Niemann, CMS Drug Payment Policy Analyst (Medicare), testified regarding how CMS interpreted the term AWP:

> Q. What did you understand Congress to be referring to in Exhibit Abbott 201 when Congress referred to 95 percent of the average wholesale price?
> A. I guess -- I don't remember -- I don't remember the content of any conversations I had with Congressional staffers that would inform on the answer to that question, but whatever they had in mind, this instruction here seems to state that same language that we've discussed ad nauseam before now as reflected in sources such as the Red Book, Blue Book or Medispan.

(10/11/07 Niemann Dep. at 366:10-21, Ex. 173.)

United States' Response: The United States does not dispute that Mr. Neimann testified as quoted. The United States disputes that Mr. Neiman testified concerning the meaning of the pertinent regulation or statute, as his testimony discusses "sources" of information rather than any definition of AWP. To the extent he testified concerning the meaning of a statute or regulation, the evidence is irrelevant and inadmissible under *United States v. Lachman*, 387 F.3d 42, 54-55 (1st Cir. 2004).

Defendants' Statement [104](h): Dr. Robert Berenson, Director of the Center for Health Plans and Providers and later as Deputy Administrator from 1998 to 2001, testified regarding how CMS interpreted the term AWP:

> Q. In any of your discussions when you worked at HCFA or CMS, did you ever use the term average wholesale price to

refer to the price at which a manufacturer sells a drug to a retail customer?
MR. DRAYCOTT: Objection.
THE WITNESS: I have no idea. I can't remember that.
BY MR. MURRAY:

Q. Do you ever remember hearing anyone else use it to mean that?

A. As I said earlier, I think there was a common understanding within the agency that AWP referred to the prices in these compendia and that they deviated from actual acquisition prices and that's how we sort of viewed AWP.

(12/18/07 Berenson Dep. at 72:21-73:3, Ex. 174.)

United States' Response: The United States does not dispute that Dr. Berenson testified as quoted. The United States disputes that Dr. Berenson testified concerning the meaning of the pertinent regulation or statute, as his testimony discusses the sources of information used for AWP pricing data rather than any definition of AWP. To the extent he testified concerning the meaning of a statute or regulation, the evidence is irrelevant and inadmissible under *United States v. Lachman*, 387 F.3d 42, 54-55 (1st Cir. 2004).

Defendants' Statement [104](I): Robert Vito, Office of the Inspector General, Regional Inspector General, testified regarding his understanding of the term AWP:

Q. . . . During your approximately thirty years at the OIG, have you understood that the term "average wholesale price" referred to prices in the compendia, such as Red Book?
MR. NEAL: Object to the form.

A. THE WITNESS: I -- I -- I believe that I understood that AWP was reported in books like the Red Book and the Blue Book

* * *

Q. When you used the term "average wholesale price," did you equate it to the prices that were in Red Book and other price listings?
MR. AZORSKY: Objection to the form.
MR. NEAL: Join the objection.

A. THE WITNESS: I believe it was listed in the Red Book and the Blue Book, yes.

(6/17/07 Vito Dep. at 135:08-15, 144:6-12, Ex. 175.)

United States' Response: The United States does not dispute that Mr. Vito testified as quoted. The United States disputes that Mr. Vito testified concerning the meaning of the pertinent regulation or statute, as his testimony discusses the sources of information used by agencies for AWP pricing data rather than any definition of AWP. To the extent he testified concerning the meaning of a statute or regulation, the evidence is irrelevant and inadmissible under *United States v. Lachman*, 387 F.3d 42, 54-55 (1st Cir. 2004).

Defendants' Statement [104](j): Linda Ragone, Deputy Regional Inspector General for OIG, testified:

Q. Okay. Did you understand Congress to be directing HCFA to pay 95 percent of the published AWP?
MR. DRAYCOTT: Objection.
A. I believe when I read that that—well, I don't—I don't have it in front of me, so I believe that it was supposed to be 95 percent of average wholesale price.
BY MR. COOK: And you understood that to be what is published in Red Book, Blue Book, Medispan, right?
A. That's what I took it to mean.

(4/18/07 Ragone Dep. at 552:1-12, Ex. 176.)

United States' Response: The United States does not dispute that Ms. Ragone testified as quoted. To the extent she testified concerning the meaning of a statute or regulation, the evidence is irrelevant and inadmissible under *United States v. Lachman*, 387 F.3d 42, 54-55 (1st Cir. 2004).

Defendants' Statement [104](k): David Tawes, Director of the Medicare and Medicaid Drug Pricing Unit, testified regarding his understanding of AWP:

A. I don't remember any specific conversations about EAC. The conversations would have been just that Medicare is required to pay 95 percent of AWP.
BY MR. TORBORG: And your understanding of that (AWP] relates to what was published in Red Book or other price listings, right?
MR. NEAL: Objection as to form. You can answer.
A. Yes.

(4/24/07 Tawes Dep. at 141:14-142:2, Ex. 177.)

Mr. Tawes agreed that the term AWP was well-understood in the industry to mean prices published in the compendia. He disagreed that changing the definition of AWP was a statutory change because there was in fact no statutory definition for AWP. He testified:

Q. Did you believe that the term "average wholesale price" was commonly understood in the industry?
MR. NEAL: Objection as to form.
A. THE WITNESS: Yes.
BY MR. TORBORG:
Q. And how was it commonly understood in the industry?
MR. NEAL: The same objection.
A. THE WITNESS: I'm not sure that I knew the exact definition that the industry would use. However, I believe that the industry obviously knew that AWPs were not based on – on wholesale prices; that it was simply a – a price for their products that they wanted to list in compendia.
BY MR. TORBORG:
Q. So it was your understanding that it was commonly understood in the industry that the term "average wholesale price" referred to prices published in pricing compendia such as Red Book or Blue Book?
MR. NEAL: Objection as to form.
A. THE WITNESS: Yes.
BY MR. TORBORG:
Q. Do you agree with the statement made in this form letter, that changing the definition of average wholesale price away from what was ever in the pricing compendia to something else was a change in Medicare statutes?
MR. NEAL: I'll object to the form.
A. THE WITNESS: No.
BY MR. TORBORG:
Q. Why not?

A. Because AWP was never defined in statute.

* * *

Q. But it was you understanding that it was commonly understood in the industry, including by members of HCFA, that AWP referred to prices published in Red Book, Blue Book, and other pricing compendia?
MR. NEAL: The same objection.
A. THE WITNESS: AWPs, yes, people knew that WPs referred to the prices that were published in – in compendia.

(4/25/07 Tawes Dep. at 481:13-484:5, Ex. 178.)

United States' Response: The United States does not dispute that Mr. Tawes testified as quoted. The United States disputes that he testified concerning the meaning of the pertinent regulation or statute, as his testimony discusses the sources of information used for AWP pricing data rather than any definition of AWP. To the extent he testified concerning the meaning of a statute or regulation, the evidence is irrelevant and inadmissible under *United States v. Lachman*, 387 F.3d 42, 54-55 (1st Cir. 2004).

105. Near the end of fact discovery, after relevant CMS officials repeatedly testified that they understood the term AWP to refer to compendia prices, Defendants once again sought to understand the factual basis for the position and statements made in an DOJ's amicus brief, purportedly made "on behalf of the Secretary of Health and Human Services" in "response to the Court's request that the Secretary explain his views on the term 'average wholesale price' (AWP), as reflected in the Medicare Act, see 42 U.S.C. §§ 1395 et seq., and federal regulations." (Dkt. No. 3104). Counsel for Abbott served the United States with deposition requests concerning "CMS's contemporaneous position during 1991-2003 concerning the meaning of AWP in any relevant Medicare or Medicaid statute or regulation," including how CMS "interpreted and applied" the term AWP in the 1991 final rule, the Balanced Budget Act of 1997, and the Medicare Modernization Act of 2003. The DOJ objected to Abbott's 30(b)(6) notice, agreeing only to produce a witness on the different question of how CMS "applied" the term AWP in the 1991 final rule and the Balanced Budget Act of 1997. The witness the DOJ designated on that topic, Don Thompson, refused to provide substantive answers on how the agency interpreted AWP—instead merely reciting that any agency interpretation would be "contained in the rulemaking record." (3/28/08 Thompson Dep. at 131:4-16, 167:3-18, 222:9-223:9, Ex. 179.)

United States' Response: The statement is disputed as unsupported argument. The United States disputes that the exhibits that Mr. Thompson "refused to provide substantive answers." Defendants' characterization of the Mr. Thompson's testimony is an expression of opinion by counsel rather than an assertion of fact, and therefore not a proper statement under Fed. R. Civ. Proc. 56. The United States further objects to defendants seeking to draw an adverse inference from the United States' proper invocation of the rules of evidence and the law of this circuit.

106. Mr. Thompson explained his understanding of the two meanings of AWP as follows:

> Q. It's simply are you aware of a common usage of the term average wholesale price by anyone?
> MR. DRAYCOTT: Objection.
> A. Again, I'm aware of two. There's the kind of regulatory Part B payment policy concept and then I'm aware of prices reflected in the compendia concept.
> Q. And I'm just trying to distinguish between the two, the first being a regulatory phrase as used in regulations and used in technical Medicare Part B payment discussions. And am I correct that when you refer to the latter you're referring to the common usage of the term average wholesale price?
> MR. DRAYCOTT: Objection.
> A. No. I guess I would -- I'm not making a distinction between the kind of common usage definition and the Medicare Part B payment policy. Where I'm drawing the distinction between the Medicare Part B payment policy and common usage definition and the prices reflected in the compendia.

(*Id*. at 119:17-120:17.)

United States' Response: The United States does not dispute that Mr. Thompson testified as quoted. To the extent he testified concerning the meaning of a statute or regulation, the evidence is irrelevant and inadmissible under *United States v. Lachman*, 387 F.3d 42, 54-55 (1st Cir. 2004).

107. Despite Mr. Thompson's testimony regarding the distinction between the Medicare Part B payment methodology plain meaning understanding of AWP and the AWP prices reflected in the compendia, CMS consistently defined AWP in its Program Memoranda, which Mr. Thompson considers part of CMS policy, as "the AWP as reflected in sources such as the Red Book, Blue Book or Medispan." (Ex. 180 (Abbott Ex. 1014); Ex. 181 (Abbott Ex. 1015); Ex. 182 (Abbott Ex. 1006); Ex. 183 (Abbott Ex. 1008); Ex. 184 (Abbott Ex. 1011).)

United States' Response: The United States disputes the statement as argument and unsupported by the cited evidence. The exhibits consist of agency instructions to carriers instructing them on how to implement the requirement that payment be based on 95 percent of AWP. Nothing in the exhibits purports to interpret the relevant statute or regulation.

108. Mr. Thompson further testified that CMS's position is set forth in Federal Register Notices:

> A. The agency's position with respect to Medicare Part B drug payment policy is contained in the Federal Register notices. So if I'm being asked to testify as to the agency's position, the agency's position is stated in its rulemaking documents.

(Thompson 3/28/08 Dep. at 128:11-128:16, Ex. 179.) When asked about language in the preamble to the November 25, 1991 final rule, Thompson testified:

> Q. Well, tell me what is the purpose of the preamble that's published to the final regulation in the Federal Register?
> A. To assist in explaining the agency's rationale for the regulations that are put into the Code of Federal Regulations.
> Q. So you would agree with me that if I were looking to determine what the phrase national average wholesale price means, the first place I would look would be to the preamble, correct?
> MR. DRAYCOTT: Objection.
> A. The first place would be the regulatory language.
> Q. Right. But if I look at the regulatory language and want additional information to tease out what precisely that language means, the first place I would look after the regulation is the preamble, correct?
> A. Correct. You would look at the preamble in its entirety and then use that to assist you with respect to 405.517.

Q. And in this instance in the preamble the agency states in this sentence that national average wholesale price is referring to the published wholesale price of the drug, correct?
A. The sentence reads "That is, we will base payment on the lower of the estimated actual acquisition cost or the published wholesale price of the drug."
Q. Right.
A. That's what the sentence says. I would agree that that's what the sentence says.

(*Id*. at 153:14-155:2.)

United States' Response: Undisputed, but irrelevant. Mr. Thompson further testified as follows:

A. From a regulatory perspective, if you look at the rulemaking documents -- so if you examined the 1991 rulemaking cycle, and then also the 1998 rulemaking cycle, the term AWP has a plain language meaning.
Q. And to be clear, your personal testimony there is that average wholesale price in the 1991 regulations is referring to an empirical average of wholesale prices?
MR. DRAYCOTT: Objection.
A. I guess what I'm saying is that in the context of the rulemaking documents, the word average means average, the word wholesale means wholesale and the word price means price. And what I'm trying to think through is does my answer change when I think about the list AWP in the compendia. And I think the answer to that question is no.

(3/28/08 Thompson Dep. at 81, 82:13-83:8, Henderson Reply Ex. 93.)

109. HHS employees have repeatedly testified that AWP is not defined or regulated in any way. For example:

Defendants' Statement [109](a): Robert Vito, one of the OIG's head auditors in charge of assembling OIG reports on AWP, stated that AWPs could not even be properly audited by the OIG because there is no regulatory or statutory definition that defines what it is, much less what a manufacturer must do: "I've testified before Congress that AWP is not defined, not auditable . . . ." (6/20/2007 Vito Dep. at 399:9-22, Ex. 185.)

United States' Response: Disputed as irrelevant, unsupported by the evidence and argumentative, except that the United States does not dispute that Mr. Vito testified as quoted.

Defendants' Statement [109](b): Dennis Smith, CMS's most senior official with respect to Medicaid testified that "[AWP] is not further defined in law or regulation . . . . There is no definition, precise." (3/27/2008 Smith Dep. at 430: 2-7, Ex. 186.)

United States' Response: The quote is incomplete and misleading. Mr. Smith testified, ". . . I would not agree that that encompasses the entirety of how AWP is relied upon by all purchasers. I think this is overly simplified. I would agree that it is not further defined in law or regulation. AWP is average wholesale price. . . Again, if I can go back, what I -- what I was referring to in saying that's I don't think how -- entirely accurate that the manufacturer is free to set any -- to set an AWP at any level." (3/27/08 Smith Dep., at 430:2-7, 430:18-21, Henderson Reply Ex. 26.)

Defendants' Statement [109](c): In April 2003, the OIG released its Compliance Program Guidance for Pharmaceutical Manufacturers. The compliance guidance was "intended to assist [pharmaceutical manufacturers] in developing and implementing internal controls and procedures that promote adherence to applicable statutes, regulations, and requirements of the federal health care programs . . . " The guidelines explicitly made clear that they were not intended as a rule and that they did not create any "new law or legal obligations." (Ex. 187 (2003 OIG Compliance Program Guidance) (Abbott Ex. 149).)

United States' Response: Undisputed, although obviously the defendants' characterization is incomplete.

110. Medicare carriers also provided testimony that they understood the term AWP to refer to prices published in the drug compendia. For example:

Defendants' Statement [110](a): Rena Clark testified on behalf of Wisconsin Physician Services ("WPS"), a Medicare carrier. Ms. Clark testified:

Q. Did CMS direct WPS where to look to obtain average wholesale price?

A. Yes.
Q. Where did CMS direct you to look?
A. There were a couple sources. The one we used most of the time was the Red Book drug topics.
Q. In your work at WPS has the term average wholesale price been synonymous with what – the prices that would be contained in the Red Book or other price listings?
MR. HENDERSON: Objection.
A. THE WITNESS: Yes.
BY MR. TORBORG:
Q. When you thought of AWP, you thought of Red Book; is that fair to say?
MR. HENDERSON: Objection.
A. THE WITNESS: That's true.

(2/8/08 Clark Dep. at 67:12-68:4, Ex. 188.)

* * * * *

Q. So if I understand correctly, in order for you to be able to use an AWP price, it has to specifically come from Red Book?
A. It doesn't have to specifically come from Red Book, but it has to specifically come from a published compendia. And a published compendia is something that's published that -- I guess it's not the manufacturer saying, we've raised the price; this is what our new Red Book amount is. It comes from the Red Book publication or Blue Book or Medispan or whatever.
Q. So if someone from Abbott had called you up and said, Ms. Clark, the AWP for Vancomycin, for example, should be $5, instead of what it was recorded in Red Book, could you use that?
A. No.
Q. And why is that?
A. Because it would not have been a published source.

(Id. at 125:3-21.)

* * * * *

Q. Okay. Is it your understanding that the law required that a carrier such as WPS use AWP prices found in published sources such as Red Book, Blue Book, or Medispan?

A. Yes.

(Id. at 160:4-8.)

United States' Response: The United States does not dispute that the witness testified as indicated, but disputes that the testimony is relevant or material. There is no evidence that Medicare carriers, much less the carrier witnesses deposed in this litigation, have ever had any authority or responsibility for making policy or interpreting the law on behalf of the United States. Their role as government contractors was and is confined to the performance of claims administration functions for Medicare Part B in accordance with instructions provided by HCFA/CMS. 42 C.F.R. § 421.210; 58 Fed. Reg. 60,789 (November 18, 1993); 57 Fed. Reg. 27,290 (June 18, 1992). The United States does not dispute that HCFA instructed carriers to use published sources such as Red Book as the source of the AWPs used to determine Medicare reimbursements for drugs. The United States also notes that it is not surprising that the carrier witnesses, whose job it was, day in and day out, to look up prices in the Red Book and determine Medicare Part B allowable amounts, would equate "AWP" with the prices in the Red Book.

Defendants' Statement [110](b): Robin Kreush Stone testified on behalf of Palmetto, a Medicare carrier. Ms. Stone testified :

A. AWP was always based off of the information published in the drug compendia sources, such as Red Book or and/or Medispan.

(2/28/08 Stone Dep. at 84:1-3, Ex. 189.)

* * * * *

Q. Ms. Stone, in calculating drug payments, did you use the compendia because you thought it reflected the prices at which providers were purchasing drugs? Or because you were directed to do so by CMS?

A. Because I was directed to do so by CMS.
Q. Is it fair to say that over the last 30 years, you have been intimately involved in calculating drug payments made by Medicare?
A. Can you repeat that again, please.
Q. Is it fair to say that over the last 30 years, you have been intimately involved in calculating drug payments for Medicare Part B?
A. No.
Q. Would it be fair to say you have been so involved in the last 20 years?
A. Yes.
Q. Based upon that experience, do you believe it's well-established in the industry that the term "average wholesale price" refers to pricing contained in the drug compendia?
A. Can you repeat that, please.
Q. From your experience, do you believe it's well-established that the term "average wholesale price" refers to pricing contained in the drug compendia?
MR. HENDERSON: Objection to the form.
A. Can you say that one more time.
Q. Sure. From your experience, is it well- established that the term "average wholesale price" refers to drug prices in the drug compendia?
A. Yes.

(2/29/08 Stone Dep. at 490:5-491:15, Ex. 190.)

United States' Response: The United States does not dispute that the witness testified as indicated, but disputes the completeness of the testimony. Ms. Stone also testified that she understood the term "average wholesale price" to mean the average of the national wholesale price:

Q. Now, you have indicated, and we have talked in great deal about the term average wholesale price.
What did you understand that term to represent?
MR. HENDERSON: Objection to the form.
Q. What did Palmetto understand that term to represent?
MR. HENDERSON: Objection to the form.
Q. Please answer.
A. The average of the national wholesale prices for a drug.
Q. Well, you sort of defined it with the term itself.

A. Yes.
Q. What did you mean by the average of the national wholesale prices of the drug?
MR. HENDERSON: Objection -- same objection.
Q. Okay.
A. The manufacturer has a wholesale price for a specific drug, and that is the average of those wholesale prices.

(2/29/2008 Stone Dep., at 331:4 - 332:4, Henderson Reply Ex. 80.)

Q. Go ahead. That's not my question. My question is: Ma'am, will you testify here under oath, that you have known for -- since the eighties, at least, that AWP is not a truly discounted price; and, therefore, does not reflect the cost to the physician or supplier furnishing the drug to the Medicare beneficiary -- you have known that for many, many years, haven't you?
MR. HENDERSON: Objection.
MR. WALKER: Objection.
A. I know the AWP is the average wholesale price. I don't know what discounts physicians are given.
MR. MOORE: Thank you for that, but I'm going to move to strike that as being non-responsive.
Q. Haven't you known for decades, that physicians and suppliers buy drugs for less than AWP?
MR. HENDERSON: Objection.
A. No.

(*Id.*, at 429:19 - 430:18.)

Defendants' Statement [110](c): Jean Veal testified on behalf of First Coast Service, a Medicare carrier. Ms. Veal testified:

Q. Is this how First Coast was directed to get the AWP when calculating payment for drugs, as published in the Red Book or similar price listings?
MR. LAVINE: Object to the form.
A. I don't know if we were instructed to use Red Book, but I think -- I don't know when this was published. Looks like 1995. But, I mean, it does look like these were instructions. I mean, I don't recall ever seeing this, but it does look like that was the instructions.

Q. Did First Coast use the term "average wholesale price" synonymous with the prices which are listed in the Red Book?
MR. LAVINE: Object to form.
A. Did we -- say that again, please.
Q. Did First Coast use the term "average wholesale price" synonymous with the prices which are referenced in the Red Book or other similar compendia?
A. I mean --
MR. LAVINE: Object to form.
A. I mean, I imagine we used the term "average wholesale price," but I don't -- I mean -- and I know there's average wholesale prices in the Red Book, but I think there's other prices in the Red Book too. I mean, I don't really understanding what you're asking.
Q. If you wanted to find an average wholesale price in your work at First Coast, you would go to the Red Book?
A. Yes.
Q. Is it your understanding that the law required First Coast to use the AWPs found in the Red Book?
MR. LAVINE: Object to form.
A. No. I mean, we weren't required to use the Red Book.
Q. What else could you have used?
A. I think the -- like this says, you could use Red Book and similar price listings. I think some of the other change requests that came out said mentioned Blue Book.
Q. Medi-Span?
A. Medi-Span.
Q. But you always believed you needed to use one of the published compendia?
A. Yes.

(3/25/08 Veal Dep. at 52:2-54:4, Ex. 191.)

United States' Response: The United States does not dispute that Ms. Veal testified as indicated. The United States disputes the relevance and materiality of the testimony. *See* United States' response to ¶ 110 above.

Defendants' Statement [110](d): Paula Walker testified on behalf of Cigna, a Medicare carrier. Ms. Walker testified:

Q. In the time that you've been at Cigna, is it fair to say that average wholesale price has largely been synonymous with the prices that you would find in the Red Book?
MR. HENDERSON: Objection.
A. THE WITNESS: I'm not sure what you mean by that.
BY MR. HALE:
Q. Well, when you think of average wholesale price, is it fair to say that you automatically think of what is contained in the Red Book?
A. Yes.
MR. HENDERSON: Objection.

(3/12/08 Walker Dep. at 60:16-61:6, Ex. 192.)

United States' Response: The United States does not dispute that Ms. Walker testified as indicated, but does dispute the SOF as incomplete. Ms. Walker also testified:

Q. Did you have any -- prior to 2004, did you have any belief as to what the average wholesale prices in the Red Book represented?
A. Average wholesale price.
Q. Did you have any understanding that those AWP numbers were totally fictional?
MS. GIULIANA: Objection.
MR. HECK: Objection.
MR. HALE: Objection.
A. THE WITNESS: No.
BY MR. HENDERSON:
Q. Did you have any understanding that those AWP numbers were the figment of someone's imagination?
MS. GIULIANA: Objection.
MR. HALE: Objection.
MR. HECK: Objection.
A. THE WITNESS: No.
BY MR. HENDERSON:
Q. Did you have a belief as to whether or not they were based on real prices?
A. I took it for what it was worth.
MS. GIULIANA: Objection.
BY MR. HENDERSON:

Q. Did you have any knowledge prior to 2004 that any manufacturers were intentionally reporting falsely inflated average wholesale prices to the Red Book?
MS. GIULIANA: Objection.
MR. HALE: Objection.
MR. HECK: Objection. Form.
MR. HALE: And to foundation.
A. THE WITNESS: No.
BY MR. HENDERSON:
Q. Did you have any knowledge -- I'm sorry. Did you have any awareness of whether or not anybody at Cigna had approved of manufacturers reporting falsely inflated prices to the Red Book?
MR. HALE: Same objection.
MR. HECK: Objection. Form and foundation.
A. THE WITNESS: No.

(3/12/08 Walker Dep. at 207:1 - 208:20, Henderson Reply Ex. 81.) *See also* United States' response to ¶ 110 above.

111. The carriers and DMERCs had discretion to include or exclude certain products in arrays. (See Dkt. No. 6189 ¶¶ 144-46.)

United States Response: The United States objects to this statement because it is vague and because the Defendants have confusingly cited as authority three different paragraphs of Abbott's 56.1 Statement (none of which even use the word "discretion") which in turn cites to several different documents thereby precluding a proper response by the United States.

The United States has described the process utilized by Medicare carriers to determine the median AWP of the generic sources of a drug. See United States' Local Rule 56.1 Statement of Undisputed Material Facts Common To All Defendants (Docket#6316), ¶¶15, 16 and 124, (Henderson Common Exhibit 3 (Helton Decl.), ¶¶ 9, 10, 18 and Henderson Common Exhibit 41 (Duggan Decl.)), ¶ 22). The United States additionally incorporates its Response (Docket #6320) to ¶¶ 144 to 146 of Abbott's Statement of Facts In Support of Its Motions for Partial Summary

Judgment and to Exclude Certain Opinions of Plaintiffs' Expert (Docket #6189). Subject to the above, the United States does not dispute that, in certain circumstances and within the confines of agency instructions and guidance, carriers had discretion to exercise judgment in determining which NDCs should be included in pricing arrays.

D. Failed Attempts To Base Part B Payments On Actual Acquisition Cost

112. In October 1991, the OIG provided comments to CMS on its proposal to pay providers at AWP. OIG suggested to CMS to require providers to bill the "lower of AWP for the specific drug used or the actual invoice price of the drug." (Ex. 165 (HHD816-0025-27).)

United States' Response: The United States does not dispute that OIG provided written comments on a CMS draft of a final rule. The document referenced in the above statement (Ex. 165) recommended that CMS "consider" requiring providers to bill an actual invoice price when it was lower that an AWP. The United States disputes the relevance of OIG's unpublished comments.

113. Kathleen Buto, the official primarily in charge of promulgating the 1991 regulation testified:

> Q. HCFA was well aware of the fact that published prices – AWP in this case – were not a reliable indicator of acquisition cost, correct?
> MR. DRAYCOTT: Objection. You can answer.
> A. HCFA had repeatedly tried to move away from the published AWPs to a better method of computing actual acquisition costs. So we were aware that AWP was not a good basis.
> Q. And in your personal view what stopped HCFA from succeeded in that effort?
> MR. DRAYCOTT: Objection. You can answer.
> A. It was probably two or three things. Politics, so a lot of concern on the part of physician groups, particularly oncologists, that, you know, they preferred the current AWP-based system for a number of reasons, didn't want to go to the burdensome and intrusive practice of having their acquisition cost collected by the agency. The lack of – except

> for the OIG studies, the lack of good data that the agency could bring forward to show the extent. And concern broadly across a variety of groups that a change would impede access to important treatment. So it was a number of things and – there's also an underlying concern of government getting into much more regulated pricing. And this would be a first step toward doing that.

(9/13/2007 Buto Dep. at 362:4-363:12, Ex. 36.)

United States' Response: Disputed that Ms. Buto was "the official primarily in charge of promulgating the 1991 regulation." Ms. Buto testified she was "involved" in the effort. (9/12/07 Buto Dep., at 253:3 - 14, Henderson Reply Ex. 21.) Undisputed that Ms. Buto testified as quoted in the remainder of paragraph 113.

114. CMS again considered paying acquisition cost rather than AWP in 1995 when Robert Neimann drafted proposed regulations to pay based on Actual Acquisition Cost ("AAC"). (Ex. 193 (Abbott Ex. 314).) According to this proposal:

> There are numerous accounts of prices for drugs charged to the Medicare program in excess of the true market place and that suppliers who bill Medicare receive discounts below the manufacturers' published average wholesale prices. In effect, the published "average" wholesale price is not the average price actually charged to wholesale customers. In order that the program can obtain the advantage of these discounts, we are adding the AAC to the drug payment methodology.

(Id. at 3.) CMS never proposed a regulation to implement this proposal. (9/14/07 Niemann Dep. at 277:4-280:1, Ex. 210.)

United States' Response: Disputed in part because Mr. Niemann testified that he could not recall whether he wrote Abbott Exhibit 314, and could not be certain if the document reflected a draft of proposed regulations under consideration by the agency. (9/14/07 Niemann Dep., at 277:16 - 278:11, Henderson Reply Ex. 82) ("The question mark is whether this was far enough along that it was actually the agency considering doing this. I don't remember."). The United

States does not dispute that CMS did not issue a notice of proposed rulemaking that reflected the contents of Abbott Exhibit 314.

115. In 1997 and 1998 the Executive Branch proposed legislation that would have changed the Medicare payment system to pay based on acquisition cost rather than AWP. (Ex. 194 (Abbott Ex. 213).) A letter from Secretary Shalala to Tom Bliley, Chairman of the Commerce Committee discusses the Executive Branch's attempts to move to an acquisition cost reimbursement system.

> Because the estimated acquisition cost approach has proved unworkable, in 1997, the President proposed legislation to pay physicians their actual acquisition costs. Physicians would tell Medicare what they pay for drugs and be reimbursed that amount, rather than the Administration developing an estimate of acquisition costs and basing payment on the estimate. Unfortunately, Congress did not adopt the Administration's proposal. Indeed the HHS Inspector General found payments based on average wholesale price data to be 11 to 900 percent greater than the prices available to the physician community. Therefore, in 1998, the President again proposed paying physicians their actual acquisition cost to "ensure that doctors are reimbursed no more, and no less, than the price they themselves pay for the medicines they give Medicare patients."

United States' Response: Undisputed, except that several sentences are omitted from the above excerpt and the excerpt is part of a much longer letter.

116. In a December 1997 radio address, President Clinton urged Congress to adopt the proposed legislation. According to President Clinton, providers who were being reimbursed at AWP were "paying just one tenth" of that to purchase some drugs. (Ex. 195 (Abbott Ex. 55).) President Clinton remarked that AWP spreads of up to 1000% weren't "even illegal; they're just embedded in the practices of the system." (*Id*. emphasis added.)

United States' Response: The first two sentences are undisputed. The third sentence is disputed as an inaccurate characterization of the document cited.

117. According to Bruce Vladeck, CMS was "not fooled into believing that it was paying actual acquisition cost." (6/1/2007 Vladeck Dep. at 382:7-16, Ex. 196.) Mr. Vladeck explained further:

Q. And so, it is fair to say that during the time you were the administrator of HCFA, the agency did not choose to change the manner in which it reimbursed Medicare Part B drugs?
MS. BROOKER: Objection. Form.
A. I would -- I would frankly personally object to that characterization because I had a growing feeling -- again, I would put this in a period probably beginning about 1995 through the time I left the government -- of frustration that we were significantly overpaying for Part B drugs, and that because of some combination, frankly, of political and legal constraints, we were unable to change it. Again, whether that was a matter of law or a matter of political judgment, whether I was clear then, I'm not clear now, but it was certainly a source of very great frustration to me that we continued to pay what I believed was excessive amounts for the drugs.
Q. And so, "choose" was a bad choice of words?
A. Yes.
Q. Okay. Did not, in fact, change the way in which it reimbursed it, for several reasons?
MS. BROOKER: Objection. Form.
A. Those methods were not, in fact, changed until 2004, I believe.
Q. You indicated that political considerations were one of the bases -- let me rephrase that. You indicated the political pressures were one of the reasons why the methodology was not changed. Correct?
A. I did, yes. That's correct.

(5/4/2007 Vladeck Dep. at 189:10-190:22, Ex. 39.)

United States' Response: Denied. The deposition questioner, and not Dr. Bruce Vladeck, stated that "HCFA wasn't overpaying because it was fooled into believing that what it was paying was actual acquisition costs." In response, Dr. Vladeck stated only, " We did not believe we were paying actual acquisition costs." (6/21/07 Vladeck Dep., at 382:7-16, Henderson Reply Ex. 83.) The further testimony cited by defendant is accurately quoted, but does not follow from the first premise, if that is what defendants suggest.

E. Medicare's Rejection Of The DOJ AWPs

118. On May 31, 2000, HHS Secretary Shalala wrote to Tom Bliley, Chairman of the Commerce Committee, responding a letter Mr. Bliley sent on May 5, 2000 concerning Medicare Part B's payment for drugs. (Ex. 194 (Abbott Ex. 213).) Ms. Shalala's letter included the following statements:

- "We have closely monitored the investigations of drug pricing conducted by the Department of Justice, the HHS Inspector General, and the State Medicaid Fraud Control Units. Let me assure you that share your concern about the significant discrepancies between the prices that Medicare must pay by law and the significantly lower prices at which physicians may obtain these drugs."
- "Because the estimated acquisition east approach had proved unworkable, in 1997, the President proposed legislation to pay physicians their actual acquisition costs. Physicians would tell Medicare what they pay for drugs and be reimbursed that amount, rather than the Administration developing an estimate of acquisition costs and basing payment on the estimate. Unfortunately, Congress did not adopt the Administration's proposal. Instead, the Balanced Budget Act reduced Medicare payment for covered drugs from 100 percent to 95 percent of average wholesale price. This recaptures only a fraction of the excessive Medicare payment amounts because, until recently, available average wholesale price data did not correlate to actual wholesale prices for certain Medicare-covered drugs."
- "Indeed, the HHS Inspector General found payments based on average wholesale price data to be 11 to 900 percent greater than the prices available to the physician community. Therefore, in 1998, the President again proposed paying physicians their actual acquisition cost to 'ensure that doctors are reimbursed no more, and no less, than the price they themselves pay for the medicines they give Medicare patients.' However, no Congressional action was taken."
- **"Current Activity**: We are now moving administratively to take advantage of the newly available, more accurate data on average wholesale prices developed for Medicaid as a result of Department of Justice investigations. These data are from catalogs of drug wholesalers, which the Department of Justice says account for a significant portion of the wholesale market. . . . To obtain the benefits of this new information for

> Medicare right away. we will provide to the insurance companies that, by law, Medicare must contract with to pay Part B claims (known as "carriers") the average of the wholesale catalog prices, just as has been calculated by First Data Bank. In June, we will send this information to Medicare carriers so they can use it when they determine average wholesale prices for their next quarterly update of Medicare drug allowances, which will become effective on October 1.2000. According to the HHS General Counsel, this is the most immediate action we can take without undergoing the formal rule-making process."

(*Id.*)

United States' Response: Undisputed.

119. In or around May of 2000, CMS Deputy Administrator Michael M. Hash drafted a memorandum to HHS Deputy Secretary Kevin Thurm regarding the DOJ AWPs. (Ex. 197 (HHD340-0031-34.) The United States, asserting the deliberative process privilege, produced only a redacted version of this document and only then after the close of fact discovery.[3] The document includes the following statement:

- The Health Care Financing Administration (HCFA) is moving ahead to implement revisions to Medicare payments for drugs using new average wholesale prices compiled by the Department of Justice (DOJ). The purpose of this memo is to update you regarding our progress."
- "Finally, we also have received a revised opinion from [Office of General Counsel] indicating that HCFA can require carriers to use the DOJ data, even without rule making. This is because the data is characterized by DOJ as more accurately reflecting average wholesale prices."

(*Id.*) (emphasis in original). When counsel for Abbott asked the Government to produce a copy of the original or revised legal opinions referenced in this document, the DOJ stated: "Mr. Cook has inquired about an OGC opinion concerning whether CMS could use an alternate source of AWPs to determine payment amounts for drugs. As we previously advised Mr. Cook, we have been unable to locate any OGC document containing this opinion and, based on our inquiries, now believe that the referenced opinion was conveyed orally by OGC staff. (Ex. 198 (3/13/09 Ltr. from J. Draycott to D. Torborg, et al.).)

[3] Abbott has asked this Court to force the United States to produce a fully unredacted version of this and other documents withheld under the deliberative process privilege. (See Dkt. No. 6260.)

United States' Response: The United States objects to defendants' attempt to re-argue issues concerning the United States' invocation of the deliberative process privilege, as such issues are obviously inappropriate for inclusion in a LR 56.1 statement, and a party's assertion of a privilege is irrelevant and inadmissible. Defendants have correctly, but selectively, quoted excerpts from the draft memorandum; however, the United States otherwise disputes the statement because the evidence does not support the assertion that Deputy Administrator Hash personally drafted the memorandum or that Deputy Secretary Thurm ever received it.

120. On or around May 18, 2000 CMS Deputy Administrator Michael M. Hash drafted a memorandum to HHS Deputy Secretary Kevin Thurm regarding the DOJ AWPs. (Ex. 199 (HHC902-214-44.) The memorandum includes the following statements:

- **Issue** We have been considering options for using the alternative average wholesale price (AWP) data provided by DOJ. While we believe that Medicare overpays for the drugs identified by DOJ we also must assure continued beneficiary access to these drugs Per your request we have met with physician and provider groups who furnish Medicare beneficiaries with the drugs on the DOJ list and conducted some impact analyses dilemma arises from the fact that delivery systems have developed around overpriced drugs Reductions in the reimbursement particularly in the magnitude contemplated by the DOJ could disrupt these systems of care. . . ."
- **Background** We recently met with organizations representing oncologists urologists the end-stage renal disease community hemophilia suppliers and suppliers of asthma equipment/drugs and home infusion therapy to discuss their concerns about our use of the DOJ alternative AWP data as basis for determining Medicare's outpatient drug allowances which are currently based on 95 percent of the AWP. . . .
- These organizations argued that 1) a high profit margin on drugs is necessary to cross-subsidize costs that are underfunded, such as drug administration; 2) beneficiaries would have limited access, as they would possibly have to receive care in more costly less convenient settings; 3) quality

of care could deteriorate since, the DOJ list does not cover all drugs and there would be substitution of potentially less effective drugs for which the inflated payment could still be obtained; 4) there is insufficient time and information to successfully implement the change, and the policy was announced without adequate comment from stakeholders – transition period was seen as critical; and 5) and in exploring an option to pay for drugs based on acquisition costs there was view that acquisition costs should include an adjustment for spillage and additional paperwork and there should not be national limit such as the median actual acquisition costs in Medicare in prior year."

- "While some of the arguments raised by these organizations appear to have merit, we do not think it is clear in every case made that Medicare payment is inadequate to cover drug administration costs, and that access and quality of care would suffer if we implement the DOJ data. Also, we can not lose sight of the fact that lower drug payments would result in lower cost-sharing and Part premiums for beneficiaries. We continue to believe that Medicare payment for outpatient drugs is excessive, and that our payment systems should be calibrated to pay correctly for covered drugs and for delivery of those drugs."

(*Id.*) The Government withheld this document under the deliberative process privilege until the Court ordered its production on November 5, 2008 after an in camera review.

United States' Response: The United States does not dispute that the United States produced a copy of the draft memorandum referenced above, and does not dispute that the draft memorandum contains the quoted language. Otherwise the statement is disputed because the evidence does not support the assertion that Mr. Hash personally drafted the memorandum or that Deputy Secretary Thurm received it, or that it reflects the official determination or views of the agency. The United States also objects to defendants' attempt to draw an adverse inference from the United States' invocation of a privilege, as such information is plainly irrelevant and inadmissible.

121. On or around June 14, 2000, CMS's Robert Berenson, Director of the Center for Health Plans and Providers, sent a decision memorandum to the CMS Administrator with the subject heading, "Medicare Average Wholesale Price (AWP) for Drug Pricing—DECISION." (Ex. 200 (HHD340-0001-04).) The United States, asserting the deliberative process privilege, produced only a redacted version of this document and only then after the close of fact discovery.

United States' Response: The United States objects to the defendants' implied criticism of the United States' proper invocation of a lawful privilege and objects to defendants' improper attempt to draw adverse inferences therefrom. Such evidence is plainly irrelevant and inadmissible. The United States also disputes the statement because the evidence does not support the assertion that former Deputy Director Berensen personally authored the memorandum prepared for his signature or that CMS Administrator ever received it.

122. On July 28, 2000, 89 members of Congress wrote to Secretary Shalala relating to the DOJ AWPs. (Ex. 201 (Abbott Ex. 220).) The Congressional members expressed their concern that "a recent administrative initiative by the Department of Health and Human Services may put Medicare beneficiaries with cancer unnecessarily at risk by denying adequate reimbursement for essential drug therapy." (Id.) They also noted that the term AWP is "a term widely understood and indeed defined by [HHS] manuals to reference amounts reflected in specified publications." (Id.) The Members stated that the "new policy does not take into account the fact that oncologists are chronically underpaid for their drug administrative services in treating cancer patients, a fact that is widely recognized." (Id.) The Congressional members further stated:

> It is disturbing that the Department would now seek to circumvent those congressional actions by redefining AWP. We see no basis for such an action in any of our previous legislation, and certainly the Department's unilateral declaration of a new definition of AWP, with no regulatory process, is inappropriate.
>
> (*Id.*)

United States' Response: Undisputed but immaterial. At the risk of perpetuating irrelevant argument, the United States further notes that in May and October of 2000, certain members of Congress sent letters to various drug companies, including Dey and Abbott, clearly

stating the view that the defendants' conduct was improper and/or illegal. (Henderson Reply Ex. 84; Henderson Reply Ex. 85) The letter to Dey, for example, stated in part,

> In fact, the Committee has learned information indicating that some companies may have increased the spread on certain drugs in a calculated and deliberate effort to use this Medicare-funded windfall as a marketing tool to induce medical providers to use their drugs, and thereby enable themselves to gain additional market share in the sale of their products. If true, such actions would not only result in the Medicare program paying far more for certain drugs than the average wholesale price, but also cause Medicare beneficiaries to pay more out of there pockets for Medicare-covered drugs and biologicals, since they are responsible for co-payment charges tied to the AWP as well. Such outcomes clearly would be unacceptable and, as Chairman of the Committee charged with oversight of certain aspects of the Medicare program. . . . If drug manufacturers are deliberately gaming the setting of reimbursement rates for such purposes, I firmly believe that they should be exposed and held fully accountable.

(Henderson Reply Ex. 84.) The letter to Abbott stated in part, "Contrary to Abbott's recent assertions in the national media, the price manipulation conduct was in no way required by or consistent with existing reimbursement laws or policies. . . . In the case of the drugs for which Abbott sought to arrange a financial kickback at the expense of government programs, the manipulated discrepancies between your company's reported AWPs and DPs versus their true costs are staggering." (Henderson Reply Ex. 85.) The views of these members of Congress ultimately won the day, as reflected in the reforms enacted in Title III of the Medicare Modernization Act, entitled, "Combatting Waste, Fraud, and Abuse." Pub. L. 108-173, Title III.

123. On September 8, 2000, CMS issued a Program Memorandum, number AB-00-86, titled "An Additional Source of Average Wholesale Price Data in Pricing Drugs and Biologicals Covered by the Medicare Program." (Ex. 202 (Abbott Ex. 138).) Program Memorandum AB-00-

86 provided alternative sources of average wholesale price data for approximately 400 NDCs, including many of the drugs at issue in the DOJ Actions. The Program Memorandum included the statement: "You are to consider these alternative wholesale prices as another source in determining your January, 2001 quarterly update for the 32 drugs (Attachment 1), as per PM AB 99-63." (Id.) CMS did not require the Medicare carriers to use the DOJ AWPs in pricing drugs.

United States' Response: Undisputed.

124. Ms. DeParle served as the CMS Administrator at the time the DOJ AWPs were introduced. Ms. DeParle testified that the "DOJ AWP" effort was a "new policy." (5/18/2007 DeParle Dep. at 290:13-292:2, Ex. 66.)

United States' Response: Undisputed.

125. On November 17, 2000, CMS issued Program Memorandum, number AB-00-115 titled "Source of Average Wholesale Price Data in Pricing Drugs and Biologicals Covered by the Medicare Program" that superseded Program Memorandum AB-00-86. (Ex. 203 (Abbott Ex. 221).) Program Memorandum AB-00-115 included the following statements:

> This is to notify you that you should NOT use the Department of Justice (DOJ) data attached to PM AB-00-86 in your next update of Medicare payment allowances for drugs and biologicals. Instead, until further notice, you should delay use of this new source of average wholesale price (AWP) and use the AWP data from your usual source.
> While we continue to believe that the AWPs reported in the usual commercially available sources are inaccurate and inflated above the true wholesale prices charged in the marketplace, congressional action may preclude the use of this alternative source. To avoid the disruption that would result from a decrease in payment allowances followed by an immediate increase due to final congressional action, we are deferring the use of the DOJ AWP data until further notice.

(*Id.*)

United States' Response: Undisputed.

126. On December 21, 2000, Congress enacted the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 ("2000 Act") which required prohibited DHHS from "directly or indirectly decreas[ing] the rates of reimbursement. under the current Medicare payment methodology . . until such time as the Secretary has reviewed the report." (Pub. L. No. 106-554, § 429(c).)

United States' Response: Undisputed, except that the description is incomplete in failing to state that the statute also directed the Comptroller General to study and make recommendations on the issue of Medicare reimbursement for drugs and to issue a report for review by the Secretary. (Pub. L. No. 106-554, § 429(a).)

127. Ms. DeParle, the CMS Administrator, testified that Congress precluded the use of the DOJ AWPs:

> Q. In the second paragraph it says that Congressional action may preclude the use of this alternative source of data. Did Congressional action preclude the use of the DOJ data?
> A. I believe it did.
> Q. And do you recall having any conversations with Congress about why Congress took that action?
> MS. YAVELBERG: Objection; form.
> A. No.
> Q. Do you know why Congress took that action?
> A. No.

(5/18/2007 DeParle at Dep. 317:2-15, Ex. 66.)

United States' Response: Undisputed.

128. In May 2003, HHS proposed a rule titled "Revisions to Average Wholesale Price Methodology" (Ex. 204 (67 Fed. Reg. 74126).) According to the Federal Register, the "rule would propose revisions to the source and methodology for determining the average wholesale price (AWP) of drugs covered by Medicare incident to a physician's service." (67 Fed. Reg. 74132-33.). The HHS further stated: "We anticipate significant savings for the program and beneficiaries from using the revised definition of AWP." (Id.)

United States' Response: Disputed. The exhibit and Federal Register to which the defendants refer, which are dated December 2, 2002 (not May 2003) do not contain any proposed rule but merely contain a brief description of then-anticipated rulemaking activity, encompassed within a larger "Statement of Regulatory Priorities" published in the Federal Register. See 67 Fed. Reg. at 74109 (December 9, 2002). The United States notes that in August 2003, CMS did issue a proposal to change Medicare drug reimbursement methodology. 68 Fed. Reg. 50428 (August 20, 2003). The proposed rule included the statement, "We note that it has been suggested that the current excessive Medicare payments for DME drugs are used to pay for inhalation and infusion services provided by DME suppliers that are not covered by the Medicare program. We believe it is inappropriate for excessive drug payments to subsidize these non-covered services." 68 Fed. Reg. at 50441. A final rule on other Medicare Part B matters, published November 7, 2003, 68 Fed. Reg. 63196, indicated the agency would not finalize new rules for Medicare drug reimbursement because Congress was considering legislation to consider the issues. (*Id*. at 63196; *see generally* 69 Fed. Reg. 1084, 1085 (Jan. 7, 2004) (explaining background)) No final changes to the drug reimbursement methodology were promulgated at that time.

F. How CMS Interprets AWP Today

129. In 2003, Congress passed the Medicare Modernization Act, which replaced the AWP methodology of payment for most drugs covered by Part B with an new paradigm, Average Sales Price ("ASP"). Congress required drug companies to report ASP pricing directly to the government. (42 U.S.C. § 1395w-3a(f).)

United States' Response: Undisputed, except that the characterization is woefully incomplete. The United States disputes that the above paragraph 129, or any of the other statements in section F of defendants' SOAF (entitled, "How CMS Interprets AWP Today") reflect

or are relevant to "how CMS interprets AWP today." Further, the United States disputes the relevance and materiality of paragraphs 129 through 133 because they relate to events after the effective date of the Medicare Modernization Act, and the United States does not seek liability or damages with respect to Medicare claims after the effective date of the MMA.

130. The Medicare Modernization Act did not change the payment basis for certain products, including vaccines and "infusion drugs" administered through durable medical equipment. (42 U.S.C. § 1395u(o(1)(A)(iv), Ex. 205 (Abbott Ex. 194). Congress maintained payment for vaccines and infusion drugs administered through durable medical equipment at 95% of AWP. (Id.) This payment methodology for vaccines and infusion drugs remains in effect today.

United States' Response: Disputed in part. For infusion drugs, the Medicare Modernization Act implemented a competitive acquisition program which would eliminate reimbursement on the basis of AWP, and retained the AWP based reimbursement only as an interim measure during the phase-in period of the competitive bidding process. 42 U.S.C.A. § 1395u(o)(1)(D)(ii); 42 U.S.C.A. § 1395w-3(a)(1)(B). Further, the defendants' statement is immaterial because only Abbott sold infusion-related products, and the MMA was passed in 2003, a full two years after the operative damages period of the Abbott case (1991 to 2001); therefore, the MMA has no bearing upon Abbott's scienter or any defense Abbott has asserted. *See* also the United States' response to ¶ 129 above.

131. Despite access to ASP, CMS uses the AWPs published in the compendia to determine payments for vaccines and infusion drugs administered through durable medical equipment. Current CMS official Elizabeth Richter testified regarding how CMS determines payment amounts for vaccines and infusion drugs administered through durable medical equipment:

> Q. Currently is the agency undertaking any effort to determine what the average price is at which wholesalers are selling drugs to their customers other than by looking it up in compendia?
> MR. DRAYCOTT: Objection. You can answer.

A. Not to my knowledge, no.
Q. So do you understand today to be the statutory command to pay average wholesale price to be satisfied by looking it up in the compendia?
MR. DRAYCOTT: Objection.
A. Yes.

(12/7/2007 Richter Dep. at 69:6-19, Ex. 206.)

United States' Response: The United States disputes the first sentence because it consists of defendants' characterization of the testimony. The United States does not dispute that Ms. Richter testified as indicated. See also the United States' response to ¶ 129 above.

132. John Warren serves as the current director of the CMS division that sets payment polices for Part B drugs. (11/06/2007 Warren Dep. At 131:16-18, Ex. 207) Mr. Warren testified regarding how CMS determines payment amounts for vaccines and infusion drugs administered through durable medical equipment:

Q. Mr. Warren, for infusion drugs are you paying, currently, 95 percent of the average price at which wholesalers sell drugs to their customers, including physicians and pharmacies?
A. We pay 95 percent of the average wholesale price that's published in the Red Book compendium.

(*Id*. at 122:12-18.) According to Mr. Warren, CMS makes no effort to look at ASP for infusion drugs:

Q. And we've already determined that when you implement the statute you look to published numbers, correct?
A. Correct.
Q. You don't look to the ASP, correct?
A. Correct.
Q. You don't seek to determine what the price is that pharmaceutical firms and wholesalers are selling drugs to retail customers, correct?
A. Right.

(*Id*. at 140:5-15.)

United States' Response: The United States does not dispute that Mr. Warren testified as indicated. See the United States' response to ¶ 129 above.

133. Mr. Warren testified regarding whether CMS changed its practice after the Court found that AWP should be interpreted in accord with its plain meaning.

> Q. Did your division change in any way the manner in which it administered the Medicare program after Judge Saris issued her opinion?
> A. We did not.
> Q. And so after Judge Saris issued her opinion you continued to pay based upon, as I understand it, published AWPs, correct?
> A. That is correct.

(*Id*. at 132:3-10.)

United States' Response: The United States does not dispute that Mr. Warren testified as indicated. See the United States' response to ¶ 129 above.

G. Cross-Subsidization

134. Kathleen Buto, Director of the Bureau of Policy Development when HHS enacted the November 25, 1991 final rule, testified regarding why CMS rejected the initial proposal to use 85% of AWP:

> Q. …Was there any connection between the removal of the 15 percent discount on AWP to concerns about shortfalls in administrative payments and the need to cover other costs associated with the administration of drugs?
> A. I'm looking at -- if you'd give me a couple seconds here, I'm looking at the response. Because I don't recall that that was the reason. But let me just look and see what we said in response to that comment. (Reading). It looks to me as if we dodged the question. In other words, they didn't respond one way or the other to whether that was at a reason for going to the alternative methodology. And I'm sure we discussed it. As a general matter, not related per se to this issue, the government doesn't like to pay for some things under one mechanism that was intended for one use and sort of overpay there in order to compensate for other costs. In reality it happens. It looks to me as if what we decided to do is avoid that whole issue, but try to say, okay, here's a compromise

> approach that we think will address general concerns about the 85 percent but also get us where we want to go, which is to pay accurately for drugs that Medicare is paying for. And that would be the survey approach that the carriers would use and the estimated acquisition cost or the actual acquisition cost.

(9/13/2007 Buto Dep. at 308:3-309:10, Ex. 36.)

United States' Response: Disputed. The quoted testimony does not address why CMS rejected a particular reimbursement proposal. Furthermore, Ms. Buto is a former CMS employee and was not testifying on behalf of the agency. Responding further, Ms. Buto testified as follows:

> Q. Would you agree with me that HCFA was aware that physicians were profiting from drugs?
> A. You know, I'll be totally transparent with you. I don't think we thought of it as profit. We understood that we were overpaying, if you will, for the drug in relation to their cost. I don't think we thought of that as profit, but in fact I know that's the way others look at it. We thought of it as an overpayment.
> Q. The next sentence says "While HCFA is impressed by a class of drugs for which Red Book AWP appears routinely to overstate real price, albeit by greatly varying amounts" -- and it continues. Was HCFA aware that the Red Book -- the difference between Red Book price and acquisition cost could be -- could vary greatly depending on the drug?
> A. We weren't -- we were only aware of that based on the OIG information. One of the flaws is that -- and I think we acknowledged this by our final policy -- we didn't have real acquisition cost data. So the point of the policy was to say we were going to try to get it. But I think the policy points to the fact that we knew there was a problem. We just didn't know what the dimension of the difference was.
> Q. If we go to the sixth page under summary and conclusions, NMC wrote "The relationship between Red Book AWP and actual purchase price is extraordinarily variable from drug to drug and across different classes of purchasers." Was that something that HCFA was aware of, that the relationship between Red Book AWP and actual purchase prices was extraordinarily variable?

A. Again, I don't think -- because we lacked the data ourselves, we heard that but we didn't have any sense that the -- you know, the actual data. So it says actual purchase prices. We didn't have actual purchase prices.
Q. But you had been advised that the differences between Red Book and actual purchase prices were extraordinarily variable?
A. If you mean by advised that people gave us that feedback, yes. We got lots of comments -- or we got some comments to that effect. But what -- you know, again, people -- as a governmental agency people make a lot of assertions in order to overturn a policy. However, we believed it was a flawed source which is why the policy came out the way it did saying we wanted to collect better data.

(9/13/07 Buto Dep. at 296:14 - 317:17, Henderson Reply Ex. 86.)

135. Ms. Buto testified regarding a question from a Carrier Medical Director on whether physicians were permitted to make a profit from Medicare Part B relating to the administration of drugs:

Q. What was the answer to Mr. Deutsch's question about whether physician is permitted to profit on the resale of the drug or biological which he administers?
A. We didn't answer the question.
Q. Didn't answer the question?
A. Did not answer the question.
Q. Did you deliberately not answer the question at the time or --
A. We deliberately stuck to the payment methodology and did not address the question directly. I think that's pretty clear.
Q. And do you know why you did not answer the question directly?
A. I don't know. But often when you don't want to answer a question directly you stick strictly to the methodology and explain what it is you do do and let people draw other conclusions. But we clearly did not address that directly.
Q. Could I read your response as stating they could profit because the carriers are reimbursing based upon average wholesale price and that was the policy?
A. What was your -- you're asking me if you could have read my response that way?

Q. Yeah. I'm trying to understand your response to the extent you did answer the question.
A. But I clearly didn't answer the question in the response. And I think – you know, we also didn't say no they can't profit. We just didn't answer the question.
Q. Was that a sensitive issue at the time?
A. I think government regulators don't like to talk about where there's profit or not profit. Even in the DRG system, the hospital system, the idea is Medicare will pay a flat amount per admission and if the hospital can produce the service for less they can keep the difference, but it's not called profit. It's called efficiency. So there's sort of an avoidance of the notion of profit. You know, again, the bedrock principles are pay fairly and in a sense try not to overregulate and let market forces sort of –

(9/12/2007 Buto Dep. at 239:22-241:22, Ex. 171.)

United States' Response: Admitted that Ms. Buto gave the quoted testimony. See also the United States' response to No. 134 above. The excerpt of testimony is incomplete, however. Ms. Buto also testified:

Q. Is that something, Ms. Buto, that you became aware of during your time at HCFA, that the use of AWP in determining reimbursement for drugs was masking the failure of Medicare and Medicaid payment policies to pay for the services?
A. That's not the way I would have -- I wouldn't have characterized it that way. You know, again, I come at it -- I came at it then from the standpoint of this is drug payment. It's supposed to be paying a fair rate. That has been shown or we believe it to be the case that it's overpaying for the drug. We should do something about that. This issue of what it was covering or compensating for, to me that's a separate issue that really needs to be taken on directly. If we should be covering these services we should be covering these services and we should do it in a straight-up way and it shouldn't be under some other mechanism. So I think of those as two separate issues and I would not have said, well, you know, a problem with AWP is it masks the, you know, the need to account for services that are otherwise needed. I

> don't -- you know, that's not the way I would have looked at it.

(9/12/07 Buto Dep., at 205:7 - 206:11, Henderson Reply Ex. 21.)

136. On February 16, 1995, in an final rule related to Medicare Coverage of Prescription Drugs Used in Immunosuppressive Therapy, CMS made the following comment regarding Medicare Part B's payment for drugs:

> Comment: One organization suggested that our payment policy cover not only the costs of drugs, but also pharmaceutical care services. The organization explained that in addition to traditional drug distribution services, contemporary pharmaceutical services include clinical functions that ensure the safe and effective use of drug therapy. Examples of these functions, which were characterized by the commenter as "pharmacy" services, are providing patient education, assessing patient compliance, and monitoring for therapeutic effectiveness and adverse effects.
> Response: Payment for functions furnished by pharmacists is included in the amount that Medicare pays for the drugs.

(Ex. 208, 60 Fed. Reg. 8951, 8953)

United States' Response: Undisputed.

137. Thomas Scully recognized the "need, both politically and substantively" to allow for cross-subsidization relating to Medicare Part B's payment for drugs. Mr. Scully testified:

> A. It is a legitimate concern for providers that the reimbursement was going to go down on the drug side. Yes. As I discussed earlier with the RUC, there was a general awareness that because oncologists in particular and rheumatologists and others had done so well compensation-wise, I mean the average oncologist salary was probably going up -- income, 25 to 30 percent all during the '90s because of this drug churn, there had probably been subconsciously in the RUC and other mechanism in Medicare an effort to kind of say, they are making so much money on drugs, why do we keep paying them money on practice expenses. So if you're going to take the money away from drugs, at least they would look at other side as a matter of equity, which we tried to say we were willing to do here.

(5/15/2007 Scully Dep. at 228:16-229:9 -29, Ex. 64.)

> Q. Because as you state here at least in some cases they are probably correct about the need for cross-subsidization, correct?
> A. Yes. As I said, the issue was whether it's 50 million or 100 million versus clearly not a one for one, but there was clearly some need, both politically and substantively to put some money back into practice expenses.

(Id. at 315:1-8..)

United States' Response: The United States disputes the first sentence as unsupported by the evidence. The United States further disputes the statement because Mr. Scully's testimony was limited to physician reimbursement for pharmaceuticals, not Part B reimbursement of drugs in general. Furthermore, he did not testify regarding any existing policy that had been implemented by CMS.

138. In 1998, Eli's Home Care Week, a trade publication, published an article regarding Medicare Part B drug payment. (Ex. 209 (Abbott Ex. 54).) The article reported that the 1998 budget gave HCFA the authority to develop a dispensing fee for drugs. Alan Parver, an attorney, is quoted in the article as stating: "It's unclear to me how, if an entity is paid its acquisition cost for a drug, it could possibly provide any services. In the infusion area, that would probably make it very difficult for a pharmacy to provide any services." (Id.) Tim Redmon, from the National Community Pharmacists Association, was quoted as stating the following:

> In the past, Redmon claims, "Medicare officials would argue that the service component was 'built into the fee schedule' for prescription drugs. Now that this component may be removed, Medicare's insistence that it 'won't pay for services' means that providers are left unable to service beneficiaries."

(Id.)

United States' Response: The United States objects and therefore disputes the statement because the evidence is inadmissible hearsay.

139. OIG's Robert Vito testified regarding Medicare Part B's payment for drugs:

Q. Do you recall conversations that you were involved in where HCFA acknowledged that respiratory [and] infusion drug providers relied upon reimbursement rates for drugs to cover services?
MR. DRAYCOTT: Objection, you can answer to the extent it doesn't reveal the contents of communications and deliberations occurring at entrance or exit conferences with CMS.
A. THE WITNESS: Yes.
* * *
Q. And do you recall having the conversations at the exit and entrance conversation, at those meetings?
A. Yes.
Q. Can you tell me about those discussions?
MR. DRAYCOTT: Objection. I instruct you not to answer to the extent it would reveal the communications and deliberations that occurred at those exit and entrance conferences.
BY MR. TORBORG: Because of that, are you accepting the instruction not to answer?
A. Yes, sir.

(2/5/08 Vito Dep. at 652:12-21, 654:2-15, Ex. 185.)

United States' Response: The United States objects to the defendants' implied criticism of the United States' proper invocation of a lawful privilege and objects to defendants' improper attempt to draw adverse inferences therefrom. Such evidence is plainly irrelevant and inadmissible.

140. In 2002, the National Alliance for Infusion Therapy/National Home Infusion Association sent a written statement to Congress. (Ex. 211 (Abbott Ex. 18).) That statement included the following comments:

- "Providers and suppliers of infusion drug therapies in the home setting are not paid separately by Medicare for the critical services and practice expenses described above. Medicare does not have a separate benefit for infusion therapy, but instead, infusion drugs provided in the home setting are covered exclusively under Medicare's benefit for durable medical equipment. The only items that are

explicitly covered and reimbursed under this limited benefit are the drugs, equipment and supplies. Unlike other health care professionals who administer infusion and injectable drugs currently covered under Medicare Part B, providers and suppliers of home infusion drug therapies do not have a mechanism under Medicare that provides them with reimbursement for the services and facilities necessary to provide these therapies."

- "This is an extremely important point for policymakers to consider as they seek to reform outpatient drug reimbursement. Since the Medicare program does not explicitly reimburse pharmacists for their practice expenses and professional services (including such home infusion services as compounding), pharmacists currently are "paid" for these costs and functions primarily through reimbursement drugs. Similarly, Medicare does not explicitly pay for nursing services provided by infusion therapy providers. A nurse performs many functions, including patient screening and assessment, patient training regarding administration of the pharmaceuticals and general monitoring of the patient's health status. To the extent that Medicare reimburses for such services, it is largely through the drug payment. As explained in greater detail below, reductions in drug payments must be accompanied by a contemporaneous re-allocation of payment for these necessary professional services. If drug payments are reduced drastically without such a re-allocation, Medicare beneficiaries will not be able to receive home infusion drug therapy because the costs of therapy will exceed by a large margin the available reimbursement for the therapy.

* * *

- "For the reasons stated above, at the present time the drug payments for infusion therapy subsidize other functions that the Medicare payment methodologies do not reflect appropriately. The costs of these services and functions far outweigh the costs of the drug product, but these costs are clearly lower than the charges that would be incurred if the patient received treatment in an alternate setting. For home infusion drug therapy, the drug payment is the only available payment mechanism for the services that are essential to providing good quality care. The long-standing use of AWP to determine reimbursement has masked the failure of

Medicare and Medicaid payment policies to define and account for the service component."

- "If changes to the methodology used to calculate drug reimbursement result in substantially reduced drug payments, without corresponding changes to ensure adequate reimbursement for the service component of providing infusion therapies, the end result will virtually guarantee an inability of providers to continue to provide these services. Without the availability of home infusion services, Medicare beneficiaries will be treated in more costly settings."

United States' Response: The United States objects to the statement on the ground that it constitutes inadmissible hearsay and is irrelevant.

141. When asked for his understanding of why Congress retained the 95% of AWP methodology for vaccines and infusion drugs administered through durable medical equipment, Tom Scully, the Former CMS Administrator, testified:

Q. And so at least for the drugs that are subject to this carveout in the home infusion setting, Congress has kept the reimbursement of those drugs at 95 percent of AWP as of --
A. As of October 2003.
Q. That's correct, isn't it?
A. I guess it is. That's what the statute says. Another piece of sausage. I have just forgotten that we did that, to be honest with you, which I assume is why they don't have a dispensing fee for anything but respiratory drugs, because they didn't do that for respiratory drugs.
Q. So it would appear that Congress, at least for these drugs and in that setting of home infusion, has determined to continue to subsidize the provision of the services by overpaying for the drugs, correct?
MR. GOBENA: Object to the form. The legislation speaks for itself.
MR. BREEN: Objection to the form.
BY MR. DALY:
Q. You can go ahead.
A. Yes. I was surprised to see this. I forgot we did it. It was certainly never discussed by members. I'm sure the staff -- staff person who wrote it works with me at Alston & Bird, so I'll go back and ask him, but I'm sure that it's probably, they froze it to freeze it, and some level of cross-subsidy apparently. I'm not sure what the congressional intent there

> was, but I think it was Senator Grassley's staff that did that provision. So I had totally forgotten we did it. That it was in the bill. It wasn't something that was widely discussed at all.

(5/15/2007 Scully Dep. at 365:22-367:10, Ex. 64)

United States' Response: Undisputed that Mr. Scully testified as quoted. However, the testimony is irrelevant and inadmissible under *United States v. Lachman*, 387 F.3d 42. 54-55 (1st Cir. 2004). The testimony is also irrelevant because there is no foundation establishing any knowledge or other basis for opining on the intent of Congress.

142. Prior to the reforms introduced by the MMA, the dispensing fee allowed for inhalation drugs under Medicare was $5. (Ex. 212, 70 Fed. Reg. 70116, 70225 (Nov. 21, 2005).)

United States' Response: Undisputed.

143. The MMA "[did] not specify a particular dispensing fee amount for inhalation drugs, nor . . . a method to determine a dispensing fee for inhalation drugs." (Ex. 213, 69 Fed. Reg. 66236, 66339 (Nov. 15, 2004).)

United States' Response: Undisputed. Congress authorized the Secretary to pay a dispensing fee in the Balanced Budget Act of 1997. Pub. L. 105-33, 111 Stat. 462-463 (1997)

144. CMS issued a proposed rule in August 2005, seeking comments on the proper dispensing fee for inhalation drugs. In its proposed rule, CMS stated: "The MMA changed the Medicare payment methodology for many Part B covered drugs. . . . Beginning with CY 2005, Medicare paid for nebulizer drugs at 106 percent of the ASP. The move to the ASP system represented a substantial reduction in reimbursement for the high volume nebulizer drugs." (Ex. 214, 70 Fed. Reg. 45,764, 45,847 (Aug. 8, 2005).)

United States' Response: Undisputed.

145. In response, CMS received a variety of comments, the majority of which cited a 2004 study by the American Association of Homecare ("AAH"), which surveyed 109 homecare pharmacies between May and July 2004. The AAH study: (1) reported that dispensing fees were inadequately low and would lead 89% of suppliers to discontinue providing inhalation drugs to Medicare beneficiaries, and (2) suggested a dispensing fee of $68.10 to cover the variety of costs associated with inhalation drugs. (Ex. 215 (Muse & Assocs., The Costs of Delivering Inhalation Drug Services to Medicare Beneficiaries).)

United States' Response: Undisputed but incomplete and irrelevant, and inadmissible because the AAH study is hearsay. The information in the AAH study and the rulemaking proceeding is irrelevant because, among other reasons, it relates to dispensing costs in 2004 or 2005, which is well before the time periods at issue in the present cases. The United States further notes that in September 2005, the HHS OIG issued a report entitled, *Review of Services Provided By Inhalation Drug Suppliers*, OEI-01-05-00090 (available at <http://oig.hhs.gov/oei/reports/oei-01-05-00090.pdf>), which questioned the validity of the conclusions in the AAH study. As explained in the report, the OIG obtained and reviewed information on services actually furnished by inhalation therapy providers, and found that a significant percentage of beneficiaries did not receive the services that the AAH study identified as giving rise to the high costs.

146. For 2004, CMS set an interim dispensing fee of $57 for a 30-day prescription of inhalation drugs, and $80 for a 90-day prescription. (Ex. 212, 70 Fed. Reg. 70116, 70225 (Nov. 21, 2005).)

United States' Response: Disputed. The $57 interim dispensing fee was for 2005, not 2004. Otherwise the statement is undisputed, but it is irrelevant for the reasons stated above, and misleading because defendants present this information out of chronological sequence. The rule-making that set the interim dispensing fee was promulgated November 15, 2004, before CMS had the benefit of the OIG report mentioned in response to paragraph 145 above. 69 Fed. Reg. 66236 (Nov. 15, 2004).

147. CMS adopted a final rule in November 2005, setting the dispensing fee at $33 (but keeping it at $57 for the first 30-day period during which an individual uses an inhalation drug). (Ex. 212, 70 Fed. Reg. 70116, 70225 (Nov. 21, 2005).)

United States' Response: Undisputed, except that the defendants' characterization is slightly inaccurate in some respects, and, in addition, the statement is irrelevant for the reasons stated above, and is incomplete. The final rule also provided for a dispensing fee of $66 for each dispensed 90-day supply of inhalation drugs.

148. In its November 15, 2004 final rule (with comment period), "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005," CMS stated:

> Finally, we note that a key purpose of the MMA legislation was to eliminate the cross-subsidization of composite rate payments by drug payments. If the composite rate was inadequate before the MMA provision, it was inadequate for both hospital-based and independent facilities. As such, increasing the composite rate by relatively greater amounts for independent facilities than hospital-based facilities would place the latter facilities at a competitive disadvantage relative to the former facilities.

(Ex. 213, 69 Fed. Reg. 66,236).)

United States' Response: Undisputed, but irrelevant because, among other reasons, the statement has nothing to do with inhalation therapy drugs or other drugs relevant to this litigation.

149. In its November 21, 2005 final rule, "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B," CMS stated:

> Response: Although some commenters stated that the dispensing fee should account for drug acquisition costs in excess of the ASP+6 percent payment, we disagree. Section 1847A of the Act specifies that the Medicare payment for inhalation drugs is at 106 percent of the ASP. We believe the Congress established the ASP based payment for inhalation drugs and separate authority for dispensing of these drugs for good reason, namely to pay appropriately for each service and to eliminate cross subsidization of services. Similarly, we believe payment for nebulizer equipment is a distinct policy separate from the dispensing fee, and one should not cross subsidize the other. In establishing the dispensing fee of $33 for a 30-day supply of inhalation drugs (and higher first month payment), we are focusing

> on what we believe is the appropriate scope and payment for the dispensing fee.

United States' Response: Undisputed, although irrelevant for reasons stated above.

IV. ADDITIONAL STATEMENTS OF FACT BY THE UNITED STATES

In further response to the defendants' Statement of Additional Facts, the United States submits the following additional undisputed facts:

149.1. Representatives of pharmaceutical manufacturers have given misleading information to the government about the role of manufacturers in setting AWPs. For example, in July of 1989, a Special Committee on Aging of the United States Senate commenced hearings, Chaired by Senator David Pryor (D. Arkansas), on spiraling drug costs in the United States. *Hearings Before the Special Committee on Aging*, S. Hrg. 101-747, 101st Cong., 1st Sess. (July 18, 1989, Nov. 16, 1989), Serial No. 101-14 (Henderson Reply Ex. 87.) Eighteen pharmaceutical manufacturers were invited to present testimony, but only one attended. However, Gerald Mossinghoff, President of the Pharmaceutical Manufacturers Association, testified and submitted a written statement. During his testimony the following exchange took place:

> SENATOR WARNER. In your prepared statement you mentioned that the so-called average wholesale price is, not really an accurate standard of what pharmacists actually pay for drugs. And this is what I was trying to get at. Why isn't it, and is there a better standard to use?
>
> MR. MOSSINGHOFF. Well, the average wholesale price is not determined by our companies. It's determined in part from surveys done of our companies. It's also done by other surveys, as I think testimony today would indicate. . .

(*Id.*, at 157.)

149.2. In October 2000, the defendants submitted a *Supplemental Analysis of Why the United States Should Decline Intervention In United States ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al.* The document asserted, in part:

> Third, the Relator cannot prove that AWPs are derived from information provided solely by the manufacturers. The federal and state governments decided to pay for drugs based on AWP as published by the commercial pricing services. This spring, First Data, the publisher of the Blue Book used by most state Medicaid programs, issued a Price Alert describing how it determines AWP by conducting surveys of drug wholesalers. In that Price Alert, First Data directly contradicted the theory of the Relator's Complaint:
>
> > Many customers are under the impression that the manufacturer sets the AWP. <u>This is not true</u>.
>
> (Emphasis added.) This year, the commercial pricing services have undertaken to revise their published prices in response to a request from state Medicaid programs. One state Attorney General described this revision as "First Data more effectively performing the task it is already required to perform." The services could always have revised their published prices in the same manner as they have this year, if HHS or the state Medicaid agencies had asked.

(Henderson Reply Ex. 88.)

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ George B. Henderson, II
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Dated: September 22, 2009